IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation Defendant.	)	Civil Action No. 04-12457 PBS

DEFENDANTS' OPPOSITION TO DEPUY MITEK'S BRIEF IN SUPPORT OF ITS CLAIM CONSTRUCTION OF THE HUNTER PATENT – U.S. PATENT NO. 5,314,446

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Table of Contents

Table of Authority

Page(s)

FEDERAL CASES

I. INTRODUCTION

It is axiomatic that the most important document in the claim construction process is the patent itself, including the claims and the specification. *See*, *e.g.*, *Phillips v. AWH Corp*., 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc). Notwithstanding this, the one consistent theme throughout DePuy Mitek's opening brief on claim construction[1] is to avoid the patent, and particularly the specification, at all costs.

For example, in connection with its proposed construction of the "basic and novel characteristics of the invention," which the parties agree must be determined by the Court, DePuy Mitek pays little more than lip service to the claims themselves and falls short of even that when it comes to the '446 patent specification. DePuy Mitek also attempts to confuse the Court by asserting that the purported reason for adding the term "consisting essentially of" to the claims somehow impacts the infringement inquiry. As described below, this is simply not true.

Further, DePuy Mitek misrepresents defendants' proposed construction of the basic and novel characteristics as including a reference to coating (where there is none). DePuy Mitek does this to try to change the argument and to assert that there was no disclaimer of coating, and therefore, coating is still in the claim. Not only does DePuy Mitek misrepresent defendants' position, but it improperly attempts to invoke the disclaimer law into the construction of the transitional phrase "consisting essentially of." DePuy Mitek's argument is exposed below for what it is -- nothing more than an attempt to create confusion where there is none.

DePuy Mitek fares no better in its proposed construction of the term "PE." DePuy Mitek adopts an approach to claim construction that was resoundingly rejected by the *en banc* Federal Circuit in its landmark *Phillips* decision. As if following a script on how *not* to construe patent claims, DePuy Mitek places extrinsic evidence above all else in its claim construction

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[1] DePuy Mitek's Brief in Support of its Claim Construction of the Hunter Patent – U.S. Patent No. 5,314,446 ("DePuy Mitek Br.").

analysis, relying on three different extrinsic sources to support its proposed construction of "PE" before it says one word about the '446 patent specification. When it does finally get around to mentioning the specification, it limits the role of the specification (as well as the prosecution history) to that of a check on the extrinsic evidence. This is precisely the approach *rejected* by the Federal Circuit in *Phillips*.

The Federal Circuit has made it abundantly clear that the patent and its prosecution history play the principal role in the claim construction inquiry. *See, e.g., Phillips,* 415 F.3d at 1315-17. While extrinsic evidence may also play a role, *Phillips* makes clear that it should be limited and approached with caution. As explained below, DePuy Mitek's proposed claim constructions have no basis in law or fact and should be rejected.

II. DEPUY MITEK'S PROPOSED CONSTRUCITON OF THE "BASIC AND NOVEL CHARACTERISTICS OF THE INVENTION" IS WRONG AND SHOULD BE REJECTED

A. Depuy Mitek's Proposed Construction Ignores The Claim Language And The Pertinent Aspects Of The Specification

DePuy Mitek acknowledges that the claim term "consisting essentially of" triggers a claim construction such that the claim excludes additional ingredients that materially affect the basic and novel characteristics of the claimed invention. DePuy Mitek Br. at 7. DePuy Mitek also acknowledges that the claim construction issue for the Court is to determine what are the "basic and novel characteristics of the claimed invention." DePuy Mitek Br. at 7. On these issues, the parties agree.

Where DePuy Mitek goes astray is in its proposed construction of the "basic and novel characteristics." DePuy Mitek proposes that the basic and novel characteristics of the claimed invention are "a heterogeneous braid of dissimilar non-bioabsorbable yarns of the materials claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that

contribute to the overall properties of the braid." DePuy Mitek Br. at 7. As we show below, this is not a correct statement of the basic and novel characteristics of the claimed invention.

DePuy Mitek must understand that the specification and the claim language play a crucial role in determining what are the basic and novel characteristics of the invention, as it asserts that its construction "is well-grounded in the *specification and the claims*" (DePuy Mitek Br. at 8) [emphasis added], and it cites case law which emphasizes that the "basic and novel characteristics [are] derived from the *specification and claim language*." DePuy Mitek Br. at 7-8 (citing *BASF Corp. v. Eastman Chem. Co.*, No. 95-746-RRM, 1998, U.S. Dist. LEXIS 23054, *24-*30 (D. Del. 1998); *Momentus Golf, Inc. v. Swingrite Golf Corp.*, 312 F.Supp.2d 1134, 1140-41 (S.D. Iowa 2004)). Yet DePuy Mitek's discussion of its proposed construction of the basic and novel characteristics never once discusses the *specific* claim language or the portions of the specification that describe the *specific* language of the claim. DePuy Mitek ignores these crucial portions of the '446 patent with good reason. It surely understands that if they *are* considered, as they must be, its proposed construction must be rejected and defendants' construction should be adopted.

The first of many problems with DePuy Mitek's construction of the basic and novel characteristics is that it is too broad. In fact, DePuy Mitek's proposed construction does not even mention the word "suture." It is simply a *braid* of dissimilar yarns where each yarn contributes a different property. But that "basic and novel" construction is equally true for prior art "heterogeneous braids" such as, for example, the Burgess application. Ex. 1. In fact, the patent examiner made this precise observation about the Burgess application (Ex. 2 at 4) and Ethicon never disputed the examiner's assertions in its response. Ex. 3. Thus, DePuy Mitek is apparently asking the Court to adopt a construction of basic and novel characteristics that is not even novel.

Including the word "suture," however, would not come close to solving DePuy Mitek's problems. The application for the '446 patent, *as originally filed*, did include a broad claim of two dissimilar fibers braided together without specifying any specific materials, similar to what DePuy Mitek now proposes to be the basic and novel characteristics of the invention. Ex. 4. That broad claim, however, was *abandoned* during prosecution. Ex. 5 at 1. Thus, although DePuy Mitek cites to certain portions of the '446 patent specification as supporting that broad claim language (DePuy Mitek Br. at 9-10), such language in the specification that relates to the broad, *abandoned* claim cannot serve as a basis for determining the basic and novel characteristics of the narrower claims being asserted.

As defendants pointed out in their opening *Markman* brief, in determining what constitutes the basic and novel characteristics, the focus must be on the claim itself because the claim defines the scope of the protected invention. Contrary to DePuy Mitek's proposed construction, the claims are *not* merely two dissimilar yarns braided together where the two dissimilar yarns have some *unspecified* different properties that contribute to the overall *unspecified* properties of the braid.

Rather, the claims are directed to a suture having two dissimilar yarns braided together where the two dissimilar yarns are selected from two groups of *specifically identified materials*. The materials identified as being in the first group are PTFE, FEP, PFA, PVDF, PETFE, PP and PE, and the materials identified as being in the second group are PET, nylon and aramid. Thus, the dispositive issue is to determine what the specification attributes as the basic and novel characteristics for a suture braid made of *these specific* materials. On this point, the '446 patent specification is crystal clear.

The specification describes the "first set of yarns" (*i.e.*, specifically, PTFE, FEP, PFA, PVDF, PETFE, PP and PE) as being "lubricating yarns to improve the overall pliability, or

compliance, and surface lubricity of the heterogeneous braid." Ex. 6 at col. 4, ll. 11-32. The specification also describes lubricating yarns as being "relatively weak and unusable." Ex. 6 at col. 2, ll. 22-24. To solve this problem, the specification describes that the "second set" of yarns (*i.e.*, specifically PET, nylon and aramid) are added to provide "improved strength." Ex. 6 at col. 4, ll. 33-40.

The specification describes that there is a tradeoff between braid strength and pliability. In the specification, this tradeoff is advantageous because the gains achieved in pliability and handleability outweigh the loss of suture strength resulting from combining a weaker, pliable material with the stronger material. According to the specification, the resulting suture is one with improved handleability and pliability performance without significantly sacrificing its physical properties. Ex. 6 at col. 2, ll. 31-37; col. 2, l. 66. That is, improved pliability and handleability on the one hand, with a minimal reduction in strength on the other, are the characteristics attributed to the specific materials recited in the claims.

DePuy Mitek is completely silent about the patent's description of a contribution to the suture braid of the specific materials identified in the claims. It is no surprise that DePuy Mitek chose silence, for if it had discussed these disclosures, as it surely should have, it would have shown that DePuy Mitek's proposal of the basic and novel characteristics cannot, and should not, be adopted.

B. The Reasons For Adding "Consisting Essentially Of" To The Claims Has No Impact On Whether An Unrecited Additional Ingredient Materially Affects The Basic And Novel Characteristics Of The Invention

DePuy Mitek goes on for pages discussing the purported reason why the term "consisting essentially of" was added to the claims during prosecution. DePuy Mitek Br. at 10-12. DePuy Mitek states that "consisting essentially of" was added to the claims to exclude bioabsorbable materials. DePuy Mitek Br. at 11. Even if DePuy Mitek were correct about the

reasons for adding this language to the claim,[2] DePuy Mitek never asserts that the reason has any impact on the claim construction of "consisting essentially of." It makes no such assertion because the reason for adding the language is irrelevant. Its inclusion in DePuy Mitek's memorandum is nothing more than a distraction designed to confuse the Court.

As DePuy Mitek correctly states, the language "consisting essentially of . . . automatically invoke[s] the novel-and-basic characteristics-of-the-invention standard." DePuy Mitek Br. at 10. And once this standard is invoked, it is well-settled patent law that infringement is avoided if the accused device contains additional ingredients that materially affect the basic and novel characteristics of the claimed invention. *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1239 (Fed. Cir. 2003). This standard for construing "consisting essentially of" claim language does not change regardless of the reason for adding "consisting essentially of" to the claim. *See, e.g., W.E. Hall Co., Inc. v. Atlanta Corrugating, LLC*, 370 F.3d 1343, 1353 (Fed. Cir. 2004) (although "consisting essentially of" was added during prosecution history, court acknowledged operation of claim term was to exclude additional elements that materially affect the basic and novel characteristics of the invention); *see also, Oscar Mayer Foods Corp. v. Conagra, Inc.*, 45 F.3d 443 at *6-*7 (Fed. Cir. 1994) (although court acknowledged patentee used the claim language "consisting essentially of" to exclude processes which reduce moisture and lower pH, court nonetheless determined the basic and novel characteristics of the invention -- which were unrelated to the excluded subject matter -- and stated that infringement is avoided if an additional step materially affects the basic and novel characteristics).

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[2] It is far from clear that the transitional term "comprising" was changed to "consisting essentially of" to exclude bioabsorbable materials from the claim, as DePuy Mitek asserts. If Ethicon really wanted to exclude bioabsorbable materials by operation of the transitional term, it could have easily written a claim using the term "consisting of," which is a closed term and would exclude anything other than the materials recited in the claim. Ethicon did not do that.

DePuy Mitek states that in *Water Technologies v. Calco, Ltd.*, 850 F.2d 660 (Fed. Cir. 1988) the "court looked to [the] prosecution history to determine what was excluded by 'consisting essentially of' language." DePuy Mitek Br. at 10. Contrary to DePuy Mitek's assertion, the court's review of the prosecution history was completely *unrelated* to the "consisting essentially of" language. There were two claims at issue in that case -- one of which was a "comprising" claim, the other being a "consisting essentially of" claim. The claim term at issue -- "triiodide" -- was in both claims. The court merely looked to the prosecution history to determine what the patentee meant by "triiodide." Thus, the *Water Technologies* case stands for nothing more than the unremarkable notion that courts look to the prosecution history to determine what claim terms mean. It is surprising that DePuy Mitek even cited *Water Technologies* because that court plainly acknowledged that the claim term "consisting essentially of" operates to exclude the addition of another ingredient which materially affects the basic and novel characteristics of the invention. *Id.* at 666. [3]

C. DePuy Mitek Misstates Defendants' Position

DePuy Mitek misrepresents defendants' proposed construction of "the basic and novel characteristics of the invention." Specifically, it states that "[p]er Arthrex, the novel and

[3] Similarly, none of the district court cases DePuy Mitek cites are helpful to it. For example, in *BASF Corp. v. Eastman Chemical Co.*, 1998 U.S. Dist. LEXIS 23054 (D. Del. 1998), the "consisting essentially of" language was *not* added by amendment based on a prior art rejection, but rather, was suggested by the examiner as a new claim. And there, the court determined the basic and novel characteristics of the claimed invention and determined that the accused product included an unrecited ingredient that affected the basic and novel characteristics. *Id.* at *29-*37. Further, in *University of Florida Research Foundation, Inc. v. Orthovita, Inc.*, 1998 U.S. Dist. LEXIS 22648 (N.D. Fla. 1998), the court determined the basic and novel characteristics of the invention -- which were unrelated to the prior art -- and acknowledged that infringement is avoided if the accused product includes other materials that materially affect the basic and novel characteristics. *Id.* at *14-*16. Moreover, in *Rheox, Inc. v. Entact, Inc.*, 2000 U.S. Dist. LEXIS 21851 (D. N.J. 2000), the "consisting essentially of" language was never at issue in the case. Rather, the only issue for the court was to decide the meaning of the claim term "calcium orthophosphate."

basic characteristics of the invention are a suture having two dissimilar yarns braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties and doing this *without a coating*." [Emphasis in original.] DePuy Mitek Br. at 12.

Nowhere in defendants' proposed construction of the basic and novel characteristics of the invention is there any mention of a coating. The coating present on Arthrex's FiberWire suture is relevant, of course, to the infringement inquiry – *i.e.*, whether coating affects the basic and novel characteristics of the claimed invention. But "coating" does not appear as a part of either parties' proposed basic and novel characteristics of the claimed invention and thus, there is no reason to discuss the issue here.

The reason for DePuy Mitek's misrepresentation soon becomes clear. It misstates defendants' claim construction -- as excluding coating -- so that it can try to change the argument to whether coating has been excluded by an "unambiguous, express, clear and unequivocal disclaimer." DePuy Mitek Br. at 13. Once again, DePuy Mitek is trying to create issues, and to sow confusion, where none exists. But even if DePuy Mitek's representation of defendants' position of the basic and novel characteristics of the claimed invention were correct, DePuy Mitek's assertion that there would need to be a clear disclaimer of coating has no legal support.[4] The process that a court should follow to determine the basic and novel characteristics of a claimed invention is simple and straightforward; examine the words of the claim and review the

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[4] In any event, DePuy Mitek's assertion that it did not disclaim coating (DePuy Mitek Br. at 13) has not been shown. As support, DePuy Mitek asserts that "the inventors specifically contemplated coatings." DePuy Mitek Br. at 13. That assertion, however, is based on a partial quote of one paragraph of the specification, leaving out the remainder of the paragraph and other critical aspects of the specification. As defendants explained in their memorandum in support of their summary judgment motion (Defendants' Mem.") at 19, when the entire specification is considered, what becomes completely clear is that the '446 patent specification criticizes the use of coating and explains that it is best to *avoid* coating. This is one of the many reasons that the inclusion of coating on FiberWire should lead to a finding of non-infringement.

specification. *See, e.g., AK Steel Corp.*, 344 F.3d at 1239. The law of "disclaimers" plays no role.

Lastly, DePuy Mitek points to one of the several portions of the '446 patent specification that clearly supports defendants' construction of the basic and novel characteristics of the invention,[5] and blithely states that Arthrex "appears to be relying on the discussion in Mitek's '446 patent of a preferred embodiment." DePuy Mitek Br. at 14. DePuy Mitek then states that the claims cannot be limited to a disclosed embodiment. DePuy Mitek misses the point. Defendants are *not* limiting the claims to the preferred embodiment, but rather are properly focusing on the characteristics of the materials *specifically identified* in the claims. As mentioned above, the broad claims of two dissimilar fibers braided together without specifying any specific materials was abandoned during prosecution. The *allowed* claims were amended to include the specific materials identified in the specification as being the preferred embodiment (*i.e.*, PTFE, FEP, PFA, PVDF, PETFE, PP and PE for the first fiber-forming materials and PET, nylon and aramid for the second fiber-forming materials). Ex. 5 at 1. Thus, what DePuy Mitek wants to call "the preferred embodiment" is not a preferred embodiment at all -- it is the embodiment that became the claims of the '446 patent.

III. DEPUY MITEK'S CONSTRUCTION OF THE TERM "PE" IS INCORRECT AND ITS CLAIM CONSTRUCTION ANALYSIS WAS RECENTLY REJECTED IN THE LANDMARK *PHILLIPS* DECISION

A. Depuy Mitek's Claim Construction Improperly Uses Extrinsic Evidence

As if it were following a script of how *not* to construe a claim term, DePuy Mitek goes about its analysis in the exact manner that was *rejected* by the Federal Circuit in its recent landmark claim construction decision, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir.

[5] The portion of the '446 patent which DePuy Mitek points to states "the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security." DePuy Mitek Br. at 14 (citing Ex. 6 at col. 2, ll. 62-66).

2005) (en banc). As defendants explained in their opening brief on claim construction, *Phillips* resolved a dispute regarding two competing methodologies on how to construe the terms of a claim -- should one begin with the intrinsic evidence (*i.e.*, the claims, the specification and the prosecution history), or should one begin with extrinsic evidence, such as dictionary definitions and expert testimony, and only consider the specification and prosecution history to see if it limits the dictionary definition.

The Federal Circuit unequivocally endorsed the approach that starts the claim construction analysis with the intrinsic evidence and rejected the approach enunciated in *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 308 F.2d 1193 (Fed. Cir. 2002), which began the analysis with dictionary definitions. In *Phillips*, the *en banc* Federal Circuit emphasized that a disputed claim term can never be viewed in a vacuum, but rather must always be interpreted in the context of the written description and the prosecution history, and reiterated that "the specification is always highly relevant to the claim construction analysis . . . and that it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1313 (citing *Vitronics Corp v. Conceptronic, Inc*., 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

The *en banc* Federal Circuit made it very clear why it chose the intrinsic evidence approach over the extrinsic evidence approach, stating that "while extrinsic evidence can shed light on the relevant art, we have explained that it is less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1317. *Phillips* also explained the reasons why it views "extrinsic evidence in general as [being] less reliable than the patent and its prosecution history in determining how to read claim terms." The Federal Circuit explained:

i) "extrinsic evidence by definition is not part of the patent and does not have the specification's virtue of being created at the time of patent prosecution for the purpose of explaining the patent's scope and meaning;"

ii) "extrinsic publications may not be written by or for skilled artisans . . . in the field of the patent;" and

iii) "extrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and this can suffer from bias that is not present in intrinsic evidence."

Phillips, 415 F.3d at 1317-18.

Turning to DePuy Mitek's claim construction of the term "PE," rather than first looking to the intrinsic evidence, as *Phillips* says one must, DePuy Mitek does the opposite. The *very first* bit of "evidence" to which DePuy Mitek points is a declaration from its expert in which Dr. Hermes concludes that "the Hunter Patent reasonably conveys to one of skill in the art . . . that the inventors had possession of a claimed suture with ultra high molecular weight polyethylene." DePuy Mitek Br. at 14-15. Dr. Hermes, in turn, points to *nothing* -- not even the '446 patent specification -- to support his conclusory statement regarding what the '446 patent teaches a person of skill in the art. This is a perfect example of what the Federal Circuit was referring to when it explained that extrinsic evidence, like Dr. Hermes's testimony, is "less reliable than the patent and its prosecution history in determining how to read claim terms."

DePuy Mitek, seemingly staying away from its own patent at all costs, next points to *additional* extrinsic evidence in the form of a technical dictionary -- the Encyclopedia of Polymer Science and Engineering (the same dictionary relied upon by Dr. Hermes, Ex. 7 at ¶ 150) -- to support its claim construction. DePuy Mitek Br. at 17.[6] In *Phillips*, the *en banc*

6 DePuy Mitek tries to create the impression that it is referring to the intrinsic evidence when it states that its claim construction "is supported by the intrinsic record." DePuy Mitek Br.

Federal Circuit warned that "[h]eavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term . . . into the meaning of the term in the abstract" and out of its proper context. *Id*. at 1321. The court further reasoned that the use of dictionary definitions can be troublesome because the applicant "did not create the dictionary to describe the invention" and thus, "there may be a disconnect between the patentee's responsibility to describe and claim his invention, and the dictionary editors' objective of aggregating all possible definitions for particular words." *Id*. at 1321.

As defendants stated in their opening *Markman* brief, the "disconnect" that troubled the Federal Circuit is the very basis for DePuy Mitek's claim construction. This dictionary, upon which DePuy Mitek now relies, expresses the very same concerns stated by the *Phillips* court 18 years later. The dictionary states that so-called source-based nomenclatures have "serious deficiencies," and predicts that as a result there will be a gradual shift "away from starting materials and toward the structure of the macromolecules." Ex. 8 at 193. When confronted with this concern and prediction expressed in this dictionary, Dr. Hermes could only state that "I don't think I have enough knowledge to disagree with those authors." Ex. 9 at 246:25 – 247:19.

But there is much more. This same disconnect is also present with regard to the other extrinsic publication relied upon by DePuy Mitek – *e.g.*, the International Union of Pure Applied Chemistry (IUPAC). DePuy Mitek Br. at 17. DePuy Mitek misrepresents this reference as "officially recogniz[ing] that 'PE' is the accepted abbreviation for all types of polyethylene." DePuy Mitek Br. at 17. However, when Dr. Hermes (who made this same contention in his report) was challenged to point out where in this reference it says that "PE is the accepted abbreviation for all types of polyethylene," Dr. Hermes meekly responded "I believe I mischaracterized the reference in the report." Ex. 9 at 244:8-14.

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at 15. However, the very next statement made in its brief -- and the next two pages -- are devoted to *extrinsic* evidence. *Id.* at 15-17.

B. Depuy Mitek's Claim Construction Is Improper Because It Limits The Role Of The '446 Patent Specification To A Check On Its Dictionary Definition

The next several pages of DePuy Mitek's brief also appear to be taken out of the rejected *Texas Digital* playbook. Just as in *Texas Digital*, DePuy Mitek compares its proposed construction of PE -- derived *exclusively* from extrinsic sources -- with the '446 patent specification to check whether its construction is limited by the specification. DePuy Mitek Br. at 17-19. This is the very approach criticized by the Federal Circuit. *Phillips* 415 F.3d at 1319. Next, DePuy Mitek asserts that the applicants did not *disavow* UHMWPE, and therefore, the term "PE" must include UHMWPE. DePuy Mitek Br. at 19-21. The Federal Circuit also criticized this aspect of the *Texas Digital* approach. *Phillips* 415 F.3d at 1319.

The Federal Circuit was very clear when it stated the methodology adopted by *Texas Digital* "placed too much reliance on extrinsic sources such as dictionaries, treatises, and encyclopedias and too little on intrinsic source, in particular the specification and prosecution history." *Phillips,* 415 F.3d at 1320. In criticizing the *Texas Digital* approach, the *Phillips* court stated that:

> [I]t suggested a methodology for claim interpretation in which the specification should be consulted *only after* a determination is made, whether based on dictionary, treatise, or other source, as to the ordinary meaning or meanings of the claim term in dispute. Even then, recourse to the specification is limited to determining *whether the specification excludes one of the meanings* derived from the dictionary, whether the presumption in favor of the dictionary definition of the claim term has been overcome by "an explicit definition of the term *different* from its ordinary meaning," or whether the inventor "has *disavowed or disclaimed* scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *In effect, the Texas Digital approach limits the role of the specification in claim construction to serving as a check on the dictionary meaning.*

Phillips, 415 F.3d. at 1320. [Emphasis added.]

The *Phillips* court concluded that "that approach, in our view, improperly restricts the role of the specification in claim construction." *Id*. Notwithstanding this clear rejection by the

Federal Circuit, DePuy Mitek adopts the *Texas Digital* approach as its own. After establishing its proposed construction of the term "PE" solely by way of extrinsic evidence -- *i.e.*, expert testimony, a dictionary and a treatise -- DePuy Mitek then states that "nothing in Mitek's '446 Patent specification or prosecution history warrants placing any limitation on the plain meaning of the term "PE.'" DePuy Mitek Br. at 17. This is the same backwards approach, rejected by the Federal Circuit, which limits the role of the specification to merely serving as a check on the alleged dictionary definition of "PE."

Not surprisingly, DePuy Mitek then proceeds to pick and choose the few portions of the '446 patent specification that, in its view, do not exclude UHMWPE from its dictionary definition of "PE." In doing so, however, DePuy Mitek *ignores* the overwhelming disclosure in the '446 patent specification that contradicts its position and plainly demonstrates that the inventors did not consider UHMWPE to be within the invention. DePuy Mitek Br. at 17-18.

PE is one of the seven polymers listed in the first set of yarns of claim 1. As defendants explained in their opening *Markman* brief,[7] the specification describes these seven polymers as "lubricating yarns to improve the overall pliability" of the braid. Ex. 6 at col. 4, ll. 11-27. The specification unambiguously states that a braid made solely of "highly lubricious yarns" will result in "a highly pliable braid." Ex. 6 at col. 2, ll. 22-24. This pliability description is the polar opposite of UHMWPE. The evidence in this case indisputably establishes that UHMWPE is stiff and *not* pliable, a fact acknowledged by DePuy Mitek's own expert, Dr. Brookstein. Ex. 10 at ¶ 56. It simply makes no sense to construe the term "PE" to include a product that makes the suture too stiff -- the exact *opposite* effect as that described in the patent. Defendants' *Markman* Br. at 11.

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[7] Defendants Arthrex, Inc.'s and Pearsalls, Ltd.'s Opening Brief on Claim Construction ("Defendants' *Markman* Br.")

The ‘446 patent specification also teaches that a braid made entirely of lubricious materials (such as the materials in the first set of yarns, including PE) would be “relatively weak and unusable.” Ex. 6 at col. 2, ll. 22-25. The notion that the lubricious polymers are too weak for suture usage is repeated when the specification cautions against using more than about 80% of the lubricious yarns because such usage “may adversely affect the overall strength of the braid.” Ex. 6 at col. 4, ll. 50-54. Defendants’ *Markman* Br. at 11-12.

Here again, it would make no sense to include UHMWPE within the meaning of “PE.” Unlike general purpose PE, UHMWPE is an incredibly strong material, one of the strongest materials known to man. It simply is not the kind of material which must be balanced against strong materials to achieve an acceptable suture. It simply makes no sense to include such a strong material in the definition when the patent teaches the exact opposite. Defendants’ *Markman* Br. at 12.

While PE is included in the group of seven materials identified for improving pliability, PE is *not* included in the group of materials identified for strength. Nor is the term PE ever associated with the “strength” yarns in the specification of the ‘446 patent. If PE included UHMWPE, one would have expected to see “PE” appear in the strength list. At a bare minimum, one would have expected to see *some* mention in the patent that “PE” could also impart strength. This is particularly true in light of the fact that Ethicon and the inventors knew that UHMWPE has great strength. Inventor Steckel testified that he knew during the development work that lead to the ‘446 patent that UHMWPE had great strength. Ex. 11 at 190:12-191:3. Likewise, when responding to an office action during prosecution, Ethicon acknowledged that UHMWPE “has great strength properties.” Ex. 3 at 2. As defendants explained in their opening brief on claim construction, there is a plain and simple reason that

there is absolutely no mention of "PE" having strength; UHMWPE was the furthest thing from the applicants' minds when they described their invention. Defendants' *Markman* Br. at 12-13.

In relying on *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 429 F.3d 1364 (Fed. Cir. 2005), DePuy Mitek attempts to create the impression that the court relied principally on extrinsic evidence to support a broad construction of the claim term "saccharides." But that is not the case at all. Rather, the *Pfizer* court recognized the importance of the intrinsic evidence -- the claims and the specification. *Pfizer*, 429 F.3d at 1373-74 (expressing the importance of considering the entirety of the patent, including the specification, and citing other portions of the patent specification to support a broader claim construction). The court conducted its analysis of both the claims and the specification and only then did it turn to the extrinsic evidence to make certain it was consistent with the intrinsic record. *Pfizer*, 429 F.3d at 1375 (only after conducting analysis of intrinsic evidence, court turned to extrinsic evidence and determined it "support[ed] the conclusion *drawn from the '450 patent*). [Emphasis added.]

Phillips does not *preclude* the use of extrinsic evidence, nor are defendants attempting to imply that it does. *Phillips* does, however, preclude placing extrinsic evidence above all else in the claim construction analysis -- as did the *Texas Digital* court and as does DePuy Mitek.

C. Depuy Mitek's Claim Construction Is Improper Because It Limits The Role Of The '446 Patent Prosecution History To A Check On Whether There Has Been A Disavowal Of Subject Matter

Like the captain of a sinking ship, DePuy Mitek does not abandon its adherence to the *Texas Digital* approach. Having arrived at its proposed construction of the term "PE" -- derived exclusively from extrinsic evidence -- DePuy Mitek then concludes that the term "PE" must include UHMWPE since UHMPWE was not disavowed in the prosecution history. DePuy

Mitek Br. at 19-21. As stated above, this backwards approach to claim construction was already rejected by the Federal Circuit. *Phillips* 415 F.3d at 1319.

DePuy Mitek tries to create the false impression that the only role served by the prosecution history during the claim construction process is to determine whether there was any disavowal of subject matter. This is simply not true. The prosecution history does not serve such a limiting role in the claim construction process. Rather, the prosecution history is part of "the indisputable public records" upon which the public is entitled to rely. *Phillips*, 415 F.3d at 1319. Even if it does not contain a clear disavowal, the prosecution history "provides evidence of how the PTO and the inventor understood the patent" since "like the specification, the prosecution history was created by the patentee in attempting to explain and obtain the patent." See, e.g., *Phillips*, 415 F.3d at 1317. The Federal Circuit has also stated that it "is often helpful in understanding the intended meaning as well as the scope of technical terms." *Vivid Technologies, Inc. v. Am. Science & Eng'g, Inc.*, 200 F.3d 795, 804 (Fed. Cir. 1999).

As defendants stated in their opening *Markman* brief, the prosecution history only serves to confirm what is made clear by the '446 patent disclosure -- that the term "PE" means general purpose PE and does not include UHMWPE. Defendants' *Markman* Br. at 11-14. During prosecution of the '446 patent, the examiner rejected the suture claims based on the Burgess application, which disclosed a fishing line made of a heterogeneous braid where the braid was made of UHMWPE and either nylon or polyester. Ethicon argued the Burgess braid would make a poor suture. In particular, the combination would be poor *because it contained UHMWPE*, a product with "minimal stretchability" and which "suffers from poor elongation." Ex. 3 at 2-3. Ethicon concluded by stating that "[e]ven if one were to look to the fishing line art, *one would inevitably design an unacceptable suture*." Ex. 3 at 3-4. [Emphasis added.] In other words, Ethicon told the patent examiner, and by extension the public (including defendants), that

the combination disclosed in Burgess – UHMWPE and polyester or nylon – would *not* make an acceptable suture. And the reason that the combination would be unacceptable was because it contained UHMWPE. [8]

Regardless of whether these exchanges between the Ethicon attorney and the PTO Examiner amount to a disavowal of UHMWPE, they are part of the indisputable public records and highly relevant to the claim construction inquiry and to how DePuy Mitek understood the '446 patent. It is clear that DePuy Mitek did not understand UHMPWE to be part of the '446 patent. No amount of spin can change this.

IV. CONCLUSION

For the foregoing reasons, DePuy Mitek's proposed claim constructions should be rejected.

[8] DePuy Mitek's reference to the prosecution history of the '446 patent (DePuy Mitek Br. at 19) is misleading because it leaves out the entirety of the substantive exchange between Ethicon and the examiner. For example, DePuy Mitek leaves out the fact that when the examiner called UHMWPE "polythene" in the rejection, the Ethicon attorney essentially corrected him and stated that the Burgess application actually disclosed "high tensile polythene." Ex. 3 at 2. The Ethicon attorney then went on for another two pages explaining why "high tensile polythene" (*i.e.*, UHMWPE) is *not* part of the '446 patent invention and why UHMWPE would not make an acceptable suture. Ex. 3 at 2-3; *see also* Defendants' *Markman* Br. at 5-6, 13-14. Far from helping DePuy Mitek, the prosecution history is strong evidence that UHMWPE is not within the meaning of PE.

Dated: September 1, 2006

Respectfully submitted,

By: /s/Charles W. Saber

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Counsel for Defendants
Arthrex, Inc. and Pearsalls Ltd.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Defendants' Opposition to DePuy Mitek's Brief in Support of its Claim Construction of the Hunter Patent – U.S. Patent No. 5,314,446 was served, via the Court's email notification system on the following counsel for Plaintiff on the 1st day of September 2006:

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EXHIBIT 1

(12) UK Patent Application (19) GB (11) 2 218 312 (13) A

(43) Date of A publication 15.11.1989

(21) Application No 8911088.8

(22) Date of filing 15.05.1989

(30) Priority data
(31) 8811498 (32) 14.05.1988 (33) GB

(51) INT CL⁴
A01K 91/00, D04C 1/12

(52) UK CL (Edition J)
A1A A19
D1K K14
U1S S1022

(56) Documents cited
None

(58) Field of search
UK CL (Edition J) A1A, D1K
INT CL⁴ A01K, D04C

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Paul David Burgess

(74) Agent and/or Address for Service
Wynne-Jones Lainé & James
Morgan Arcade Chambers, 33 St. Mary Street, Cardiff, Glamorgan, CF1 2AB, United Kingdom

(54) Improvements relating to fishing lines

(57) A fishing line of braided construction has some filaments of high tensile polythene. The other filaments are of polyester and/or nylon, and the braid may be coated with a sheath of polyurethane.

GB 2 218 312 A

2218312

"Improvements relating to Fishing Lines"

This invention relates to fishing lines.

Fishing lines require many qualities, such as high tensile strength, while having a small diameter, non-stretchability, resistance to abrasion, smooth running and suppleness. It is the aim of this invention to provide a line embodying most of these not usually very compatible properties.

According to the present invention there is provided a fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

The high tensile polythene gives the line minimal stretchability and will preferably be a high molecular weight polythene, melted in a solvent and drawn at high speed into extremely fine strands. This produces almost perfect alignment of all the molecules in long chains. A suitable product is that sold under the Registered Trade Mark DYNEEMA.

With polyester, multifilaments will generally be used, and the more there are of them in proportion to the polythene the stiffer the line will be. With nylon, monofilaments will preferably be used and the principal effect will be a low coefficient of friction.

It would be possible for certain applications to combine both polyester and nylon with the polythene thread.

The braid may be coated with a thin, supple and smooth sheath of polyurethane and this may be carried out by a simple immersion process in liquid polyurethane. It will alter the characteristics (such as buoyancy and strength) in a predictable manner, but its main purpose is to prevent saturation of the interstices of the braid. In very cold conditions, such as fishing through holes in ice, water having worked its way into the braid will freeze and impart a brittleness that can lead to breakage.

SL/SCS

CLAIMS

1. A fishing line of braided connstruction, some braid filaments being of high tennsile polythene thread and other filaments being of poilyester and/or nylon.

2. A line as claimed in Claim 1,, wherein the other filaments include polyester muulti-filaments.

3. A line as claimed in Claim 1 or 2, wherein the other filaments include nylon monoofilaments.

4... A line as claimed in Claim 1., 2 or 3, wherein the braid is coated by a sheath of polyyurethane.

5. A line as claimed in any preeceding Claim, wherein the polythene is that sold undeer the Trade Mark DYNEEMA.

Published 1989 at The Patent Office, State House, 66/71 High Holborn, London WC1R 4TP. Further copies may be obtained from The Patent Office. Sales Branch, St Mary Cray, Orpington, Kent BR5 3RD. Printed by Multiplex techniques ltd, St Mary Cray, Kent, Con. 1/87

EXHIBIT 2

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/838,511	02/19/92	HUNTER A	ETH-782

EXAMINER	
RAIMUND, C	
ART UNIT	PAPER NUMBER
1504	3

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

DATE MAILED: 07/08/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on ______ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice re Patent Drawing, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ ______

Part II SUMMARY OF ACTION

1. ☑ Claims 1 - 24 are pending in the application.

   Of the above, claims 1 - 20 are withdrawn from consideration.

2. ☐ Claims ______ have been cancelled.
3. ☐ Claims ______ are allowed.
4. ☑ Claims 21 - 24 are rejected.
5. ☐ Claims ______ are objected to.
6. ☑ Claims 1 - 24 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on ______. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on ______ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on ______, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ______; filed on ______.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

PTOL-326 (Rev. 9-89)

EXAMINER'S ACTION

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000186

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-20, drawn to a heterogeneous braid, classified in Class 57, subclass 243.

II. Claims 21-24, drawn to a surgical suture, classified in Class 600, subclass 231.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as mutually exclusive species in intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (M.P.E.P. § 806.04(b), 3rd paragraph), and the species are patentably distinct (M.P.E.P. § 806.04(h)).

In the instant case, the intermediate product is deemed to be useful as a fishing line and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Matthew S. Goodwin on June 23, 1992 a provisional election was made without traverse to prosecute the invention of Group II, claims 21-24. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-20 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 21-24 are rejected under 35 U.S.C. § 103 as being unpatentable over Burgess (U.K. Patent Application No. 2,218,312A).

Burgess discloses a fishing line of braided construction comprising filaments of polyethylene and filaments of polyester or nylon. Such a braid is disclosed to have the low stretchability of polyethylene and the low coefficient of friction of polyester. (See page 1). It is therefore known to braid filaments of two dissimilar polymers together to form a structure which embodies the desirable properties of each fiber.

Braided sutures are well known in the art. Many of the requirements of sutures are comparable to those of fishing line-strength, low stretchability, flexibility, low coefficient of friction etc. Indeed, many of the same materials are used for both of these applications. It would therefore have been

obvious, in view of Burgess, to use a heterogeneous braid for a suture. Claims 21 and 23 are therefore unpatentable over Burgess.

Synthetic, fiber forming polymers are widely employed as filaments in braided sutures. In German Patent Application DE 2949920A1, for example, surgical sutures made from braided polytetrafluoroethylene (PTFE) fibers or polyester fibers are disclosed. As polyester fibers are noted for their strength and PTFE fibers for their low coefficient of friction, it would have been obvious to use a braid comprising both types of filaments as a suture.

It is also known in the art to a braid around longitudinally extending core filaments. Ohi et al, for example, disclosure a core comprising a plurality of synthetic fiber filaments (column 1, lines 57-60). Polyester filament are specifically disclosed (column 2, lines 4-9). It would therefore have been obvious to dispose a heterogeneous braid comprising polyester and polytetrafluoroethylene fibers around a core of polyester fibers to form a suture. Claims 22 and 24 are therefore unpatentable over Burgess.

Any inquiry concerning this communication should be directed to Chris Raimund at telephone number (703) 308-3452.

Chris Raimund

Chris Raimund:jp
July 06, 1992

GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150

EXHIBIT 3

MAIL ROOM AUG 10

ETH-781

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair Hunter et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 6, 1992
(Date of Deposit)

Matthew S. Goodwin
Name of applicant, assignee, or Registered Representative

Matthew Goodwin
(Signature)

August 6, 1992
(Date of Signature)

RECEIVED
AUG 17 1992
GROUP 150

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

Responsive to the Office Action of July 8, 1992, please reconsider the above-identified application in view of the following remarks.

REMARKS

1. Restriction to the invention of either Group I, claims 1-20, or Group II, claims 21-24, was required. Applicants reaffirm without traverse to prosecute the invention of Group II, claims 21-24. This election is made without prejudice to Applicants' right to file a divisional application directed to the non-elected invention of Group I, claims 1-20.

2. Claims 21-24 were rejected under 35 USC §103 as being unpatentable over Burgess. The Examiner has asserted that it would have been obvious in view of Burgess to use a heterogeneous braid for a suture. Applicants respectfully traverse this rejection.

The Examiner mistakenly believes that the requirements for a braided suture are comparable to those of a fishing line. However, nothing could be further from the truth.

One of the most important requirements for a braided suture is that it have outstanding knot strength when a knot is secured on the suture braid. Indeed, this requirement may be the most important requirement for a braided suture. This is so because the suture knot is what keeps a stitched wound intact. If the knot fails, then the wound can reopen and consequently the braided suture has failed as well.

Applicants recognized the importance of knot strength when attempting to overcome the shortcomings of the braided sutures disclosed in the art. In preferred embodiments of the invention, Applicants' claimed suture exhibits improved handling properties without sacrificing physical strength or knot security (see the specification at page 5, lines 4-7). In addition, numerous braided sutures were tested to determine their knot strength and knot security (see the examples at the end of the specification). The determination of knot security is described in the specification at page 12, lines 26-33.

In contrast, knot strength is not even mentioned in Burgess. Although it may be argued that it may be necessary to secure a knot on a fishing line to hold the hook to the line, the security and strength of the knot are not nearly as critical for this application. In fact, the fishing line of Burgess would have poor knot strength properties because of its braided construction, as set forth in more detail below.

Some of the braid filaments of the Burgess fishing line are composed of high tensile polythene thread. This thread gives the line minimal stretchability (see Burgess at page 1, lines 12-13). Although this thread has great strength properties, it suffers from

low elongation and, in turn, poor knot strength properties. This is a good idea for a fishing line because high strength and low elongation, or low stretchability, are important criteria. Low elongation is an important requirement for a fishing line because it makes it possible for the fisherman to apply force on the hook when, for example, the fish is caught. If the line were stretchable, then the force exerted by the fisherman would be taken up by the stretching action of the line. This would clearly be an undesirable property for a fishing line to exhibit. Therefore, the property requirements for fishing line yield a braid with <u>poor</u> knot strength and security, and the requirements for sutures yield a braid which has by necessity <u>excellent</u> knot strength and security.

In addition to the contrasting requirements for braided sutures and fishing line resulting from the critical need to tie strong and secure knots on braided sutures, other requirements concerning the knot make the braid for a fishing line unsuitable for use as sutures. For example, a surgeon must be able to make a conventional square knot at a very fast pace for patient safety. Clearly, a knot on a fishing line for a hook can be made at a much slower pace, and with a much more complex knot. Also, it is necessary during suturing to form a pre-knot on the braided suture, and the pre-knot must be subsequently slid down the suture until it is adjacent the body tissue desired to be stitched. Once the knot is placed at the desired location, additional throws on the knot can be added for knot security. This requires a braided suture which is stretchable and resilient so that this operation can be performed. Obviously, there is no such similar requirement for a fishing line.

In view of the dissimilarities in property requirements between sutures and fishing line, there would simply be no incentive for a medical designer who wishes to improve the properties of braided sutures to study the art related to braided fishing lines. Even if he did use the teachings of the fishing line art to modify a

suture, then he would inevitably design an unacceptable suture. Accordingly, Applicants respectfully submit that the rejection is in error and therefore it should be withdrawn.

It is noted that the Examiner has discussed German Patent Application DE 2949920 A 1 and Ohi et al. as evidence of the state of the art concerning the types of filaments used in braided sutures, and core/sheath braid construction. Applicants do not wish to rely on these specific limitations set forth in claims 22 and 24 for patentability, but instead rely on the inventive features set forth in the broader independent claim, claim 21.

Accordingly, for the reasons set forth above, Applicants respectfully request the Examiner to withdraw the rejection of claims 21-24 under 35 USC 103 as being unpatentable over Burgess.

3. Since all formal requirements appear to have been met, except for the submission of formal drawings, and claims 21-24 are patentable over the art of record, Applicants respectfully solicit a Notice of Allowability.

Respectfully submitted,

Matthew S. Goodwin
Attorney for Applicant
Reg. No. 32,839

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
August 6, 1992

EXHIBIT 4

3

[redacted]

838511

TITLE OF THE INVENTION

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

ETH-782

VIA EXPRESS MAIL NO. HB346860118
MAILED FEBRUARY 19, 1992

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U.S. Patent 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Patent 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

FB

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Patent 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

FB

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Patent 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite

3

sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by Figure 3 which is described in detail below), apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

CL

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying

the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

DRCL

BRIEF DESCRIPTION OF THE DRAWINGS

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Figure 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

Figure 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

Figure 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

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DETAILED DESCRIPTION OF THE INVENTION

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For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at

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least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Patent Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Patent Nos. 4,959,069 and 5,059,213.

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The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns,

respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ϵ-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

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Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle

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of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below

9

about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of Figure 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and 24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of Figure 1 are dispensed upward

with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in Figure 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing

stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Patent 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is

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determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

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EXAMPLES

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Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Patent 4,470,941.

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CONTROL I

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FIBER MATERIALS: An 8x0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

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PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each

carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225 C°.

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CONTROL II

PB33

FIBER MATERIALS: An 8x0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

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PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

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EXAMPLE I

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FIBER MATERIALS: An 8x0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

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PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm.

The braid is scoured and hot stretched per the conditions described in CONTROL I.

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EXAMPLE II

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FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

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PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

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PRIOR ART I

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FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

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PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300 C° and for a longer residence time to facilitate melting of the PET fibers.

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The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY ($gmXcm^2$)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.87			0.0966	

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As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

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$$P_c = (Vf_a)\ (P_a) + (Vf_b)\ (P_b)$$

PSPSH

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in Figure 2, which shows a plot of tensile strength versus

volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in Figure 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the <u>bending moment-radius of curvature</u> plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Patent 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and Figure 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

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WHAT IS CLAIMED IS:

1. A heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and:

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

2. The heterogeneous braid of claim 1 wherein the first and second fiber-forming materials are nonmetallic.

3. The heterogeneous braid of claim 2 wherein the first and second fiber-forming materials are synthetic fiber-forming polymers.

4. The heterogeneous braid of claim 3 wherein the synthetic fiber-forming polymers are bioabsorbable.

5. The heterogeneous braid of claim 4 wherein the bioabsorbable polymers are derived from a monomer selected from the group consisting of glycolic acid, glycolide, lactide, p-dioxanone, ϵ-caprolactone, trimethylene carbonate, and mixtures thereof.

6. The heterogeneous braid of claim 3 wherein the fiber-forming polymers are nonabsorbable.

3 ~~7~~. The surgical suture ~~heterogeneous braid~~ of claim 1 ~~6~~ wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4 ~~8~~. The surgical suture ~~heterogeneous braid~~ of claim 3 ~~7~~ wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

~~9. The heterogeneous braid of claim 8 wherein the first set of yarns is PTFE, FEP, PFA, PVDF, PETFE, PP or PE.~~

5 ~~10~~. The surgical suture ~~heterogeneous braid~~ of claim 4 ~~9~~ wherein the first set of yarns is PTFE.

6 ~~11~~. The surgical suture ~~heterogeneous braid~~ of claim 5 ~~10~~ wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7 ~~12~~. The surgical suture ~~heterogeneous braid~~ of claim 6 ~~11~~ wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

~~13. The heterogeneous braid of claim 12 wherein the second set of yarns is PET, nylon or aramid.~~

8 ~~14~~. The surgical suture ~~heterogeneous braid~~ of claim 1 ~~13~~ wherein the second set of yarns is PET.

~~15. The heterogeneous braid of claim 14 wherein each yarn from the first set is in direct intertwining contact with a yarn from the second set.~~

~~16. The heterogeneous braid of claim 15 wherein the braid encloses a core of longitudinally extending yarns.~~

ETH-782

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17. The heterogeneous braid of claim 16 wherein the longitudinally extending yarns are PET.

~~18~~ 9. The ~~heterogeneous braid~~ surgical suture of claim ~~17~~ ~~14~~ 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

~~19~~ 10. The ~~heterogeneous braid~~ surgical suture of claim ~~18~~ 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

~~20~~ 11. The ~~heterogeneous braid~~ surgical suture of claim ~~1~~ ~~21~~ 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

~~21~~. A surgical suture comprising the heterogeneous braid of claim 1.

22. A surgical suture comprising the heterogeneous braid of claim 19.

~~23~~ 2. The surgical suture of claim ~~21~~ 1 wherein the suture is attached to a needle.

~~24~~ 12. The surgical suture of claim ~~22~~ ~~14~~ 8 wherein the suture is attached to a needle.

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07/838,511

ABSTRACT

SA

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

PA

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

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EXHIBIT 5

AUG 9 1993

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 4, 1993
(Date of Deposit)

Hal B. Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

August 3, 1993
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

This amendment is responsive to the Office Action of March 18, 1993.

SEP 1 1993

IN THE CLAIMS

Please amend claim 21 as follows:

(Once Amended)

1 ~~21~~. A surgical suture [comprising] consisting essentially of a [the] heterogeneous braid [of claim 1] composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

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CLAIM 2

REMARKS

Please note that the attorney prosecuting this application for the assignee, Johnson & Johnson, is now Hal Brent Woodrow (Reg. No. 32,501). This change has been authorized by the Associated Power Attorney submitted herewith. No change in the address for correspondence is necessary.

Claim 21 has been amend to place this claim in proper form for allowance. Claim 21 as amended claims a heterogeneous braid composed of a first and second set of yarns. The first set of yarns are made of a fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP, and PE materials. The second set of yarns are made of a fiber-forming material selected from the group consisting PET, nylon and aramid materials. Support for there amendments may be found in the specification on page 4, lines 12-22 and page 8, lines 3-23. Accordingly, applicants request entry of this amendment and reconsideration of claim 21.

The rejection of claim 21 under 35 U.S.C. §102(e) as being anticipated by Kaplan et al. has been reviewed. However, applicants respectfully submit that claim 21 as amended is not anticipated by Kaplan. Kaplan, as stated by the Examiner, describes a connective tissue prosthesis comprising a braided sheath yearn component and a core yarn component. The sheath yarn being a biocompatible yarn that is bioabsorbable or semi-bioabsorbable (column 9 lines 10-12). In one embodiment the sheath yarn could also contain a non-bioabsorbable yarn of one or more chemical composition (column 9 line 25-27). Claim 21 as amended does not claim a sheath yarn composed of a bioabsorbable yarn. Accordingly, Kaplan et al. does not anticipate claim 21 under 35 U.S.C. § 102(e). Therefore, applicants request reconsideration and withdrawal of the rejection of claim 21 as being anticipated by Kaplan et al.

Applicants have also reviewed the rejection of claims 21-24 under 35 U.S.C. § 103 as being unpatentable over Doddi et al. taken with Kaplan et al. However, applicants respectfully submit that claims 21-24 are patentable over these documents.

Doddi et al. describes (column 9, lines 46-56) multifilament sutures composed of p-dioxanone and/or 1,4 dioxepan-2-one and alkyl substituted derivatives that may be woven, braided or knitted, either alone or in combination with nonabsorbable fibers. Although Doddi is a significant contribution to the art, Doddi does not describe heterogeneous braids formed from a first set of yarn composed of a plurality of filaments formed from materials selected

from the group consisting of PTFE, FEP, PFA PVDF, PETFE, PP and PE; and a second set of yarn composed from a plurality of filaments formed from materials selected from the group consisting of PET, nylon and aramid. Accordingly, Doddi alone would not render the present invention obvious.

Kaplan et al. as discussed previously describes a prosthesis comprising a core component and a braided sheath component. The sheath component which is designed to "erode over time" (column 9, line 52) to leave only the nonabsorbable core component. The sheath, however, may optionally have, in addition to the bioabsorbable sheath yarn, one or more non-bioabsorbable filaments. Applicants, therefore, respectfully submit that Kaplan does not suggest or disclose combining a first set of nonabsorbable yarns (i.e. PTFE) and a second set of nonabsorbable yarn (i.e. PET). In fact, Kaplan teaches away from this combination.

In column 2, Kaplan describe one of the objects of their invention as being "a prosthesis being formed of a composite yarn wherein an elastic core yarn is wrapped with a relatively inelastic, bioabsorbable or semi-absorbable sheath yarn so as to exhibit the stress-strain properties of natural tissue" (column 2, lines 36-41). In column 4, Kaplan describes fluorinated hydrocarbons, polypropylene and polyethylene as elastic core polymers as opposed to the inelastic sheath polymers desired in the sheath. Thus, Kaplan appears to suggest that the sheath yarns listed by the applicant in claim 21 should not be used as in sheaths. Applicants respectfully submit that in view of Kaplan teaching away from the present invention that the combination of Kaplan with Doddi does not render the present invention obvious. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 21-24.

The citation of Block (U.S. Patent No. 3,527,650) has also been considered, but is respectfully submitted to be non-analogous art. Block describes the use of PTFE particles on the external surface of a PET suture as a lubricant. Block, however, does not suggest or disclose PTFE fiber as having a lubricating effect. Therefore, Block's use of PTFE particles does not suggest or disclose the use of PTFE fibers in braids.

Applicants also wish to alert the Examiner to the applicants' intent to change the inventorship because of the reduced scope of the claims. Dennis D. Jamiolkowski will no longer appear as an inventor if the present claims are allowed. Papers to effectuate this changed inventorship will be submitted when one or more of the present claims are indicated to be allowable.

Respectfully requested,

Hal Brent Woodrow
Hal B. Woodrow
Reg. No. 32,501

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
Date: August 31 1995

EXHIBIT 6

US005314446A

United States Patent [19]

Hunter et al.

[11] Patent Number: 5,314,446

[45] Date of Patent: May 24, 1994

[54] **STERILIZED HETEROGENEOUS BRAIDS**

[75] Inventors: **Alastair W. Hunter**, Bridgewater; **Arthur Taylor, Jr.**, Plainfield, both of N.J.; **Mark Steckel**, Maineville, Ohio

[73] Assignee: **Ethicon, Inc.**, Somerville, N.J.

[21] Appl. No.: **838,511**

[22] Filed: **Feb. 19, 1992**

[51] **Int. Cl.**[5] **D04C 1/00**

[52] **U.S. Cl.** **606/231**; 606/228; 87/7; 87/9; 428/370

[58] **Field of Search** 606/228, 230, 231; 87/7, 8, 9; 428/225

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Primary Examiner—George F. Lesmes
Assistant Examiner—Chris Raimund
Attorney, Agent, or Firm—Hal Brent Woodrow

[57] **ABSTRACT**

Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

FIG-1

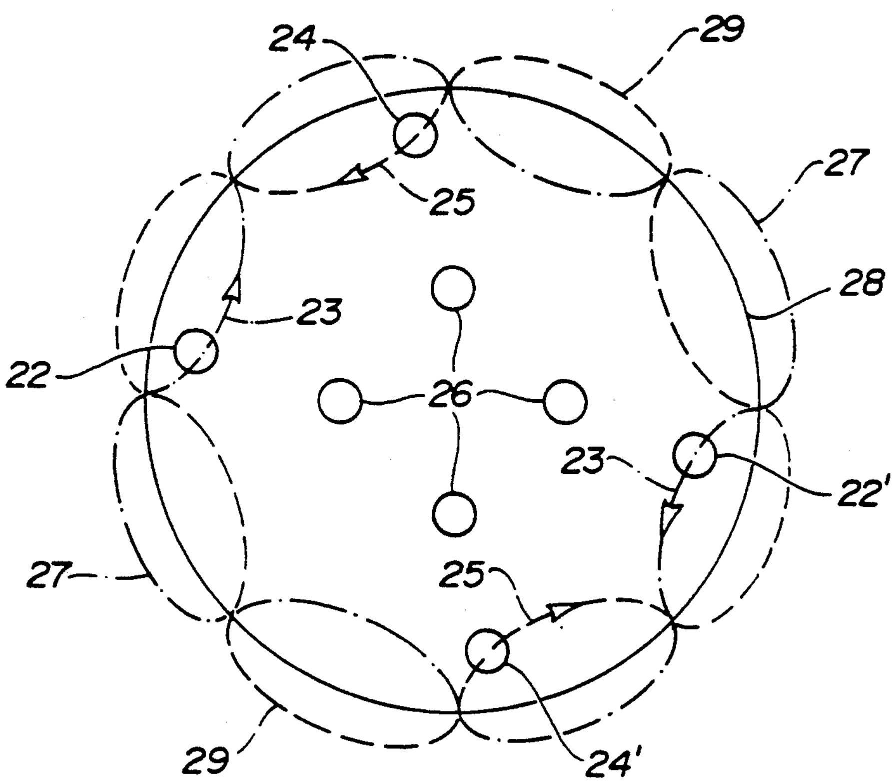
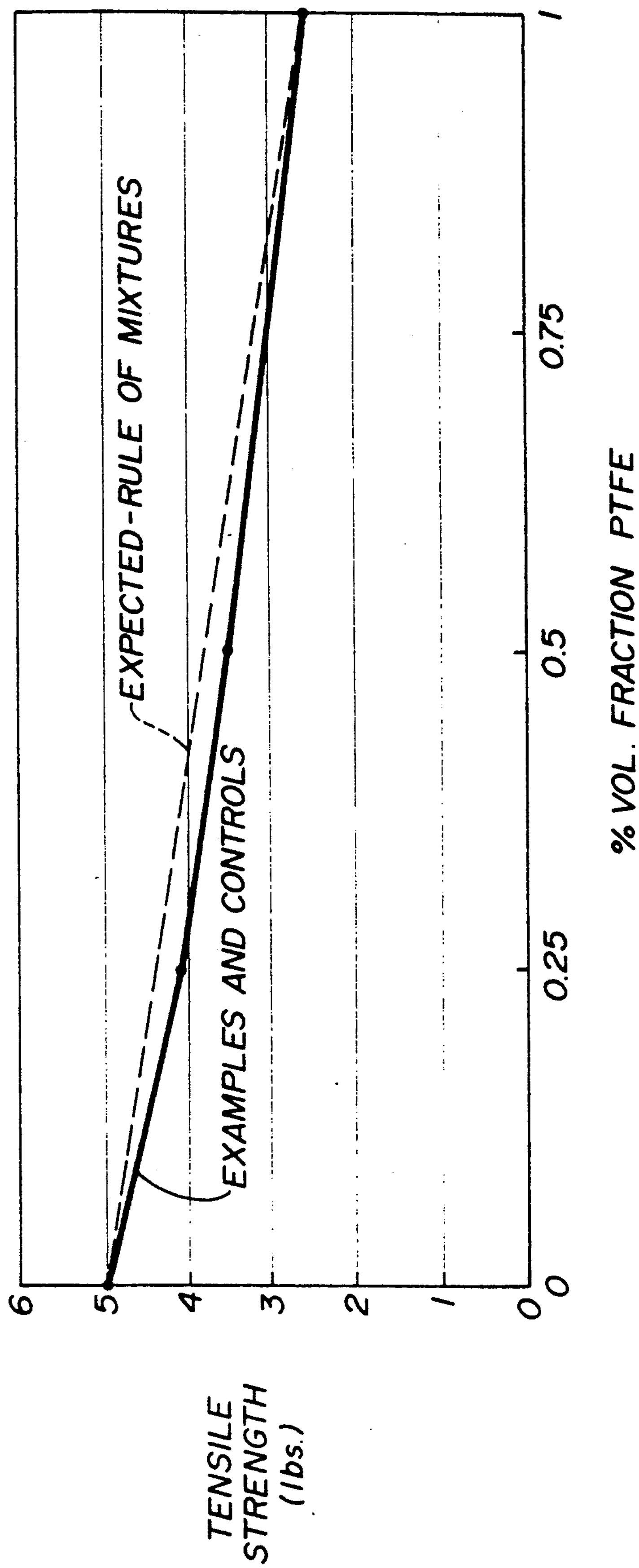


FIG-2


EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
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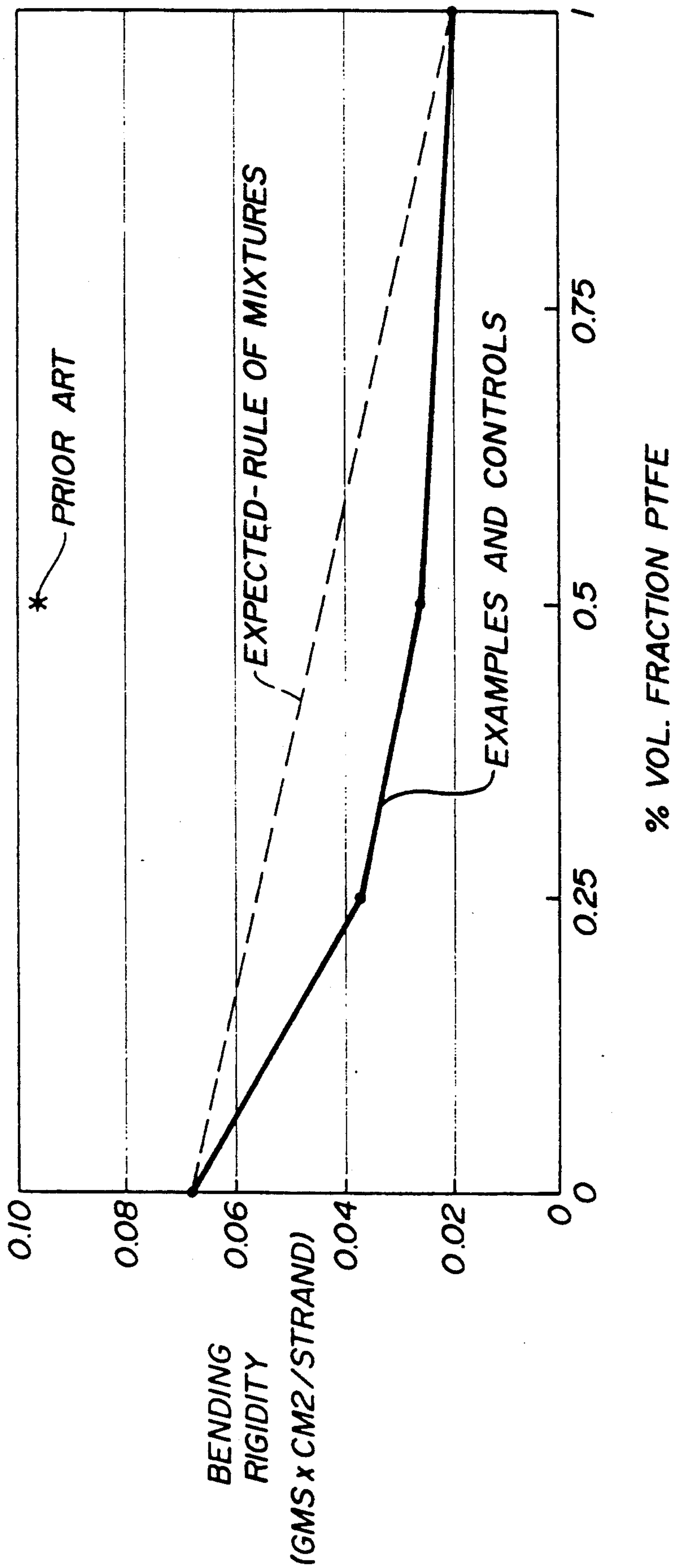
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-3


PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
% VOL. FRACTION PTFE
0
0.25
0.5
0.75
1
0.10
0.08
0.06
0.04
0.02
0
BENDING RIGIDITY (GMS x CM2/STRAND)

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below), apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone,

ε-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers **22**, **22'** and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves

braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm^2)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c=(Vf_a)\,(P_a)+(Vf_b)\,(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

* * * * *

EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)))))))))))))))	**Civil No. 04-12457 PBS**

Expert Report of Dr. Matthew Hermes

I. Background Information

A. Professional Experience

1. From 1983-95, I was employed with U. S. Surgical Corp. In 1983, I started as Senior Research Scientist. My duties from 1983-1986 included developing products based on bio-absorbable materials for use as medical devices. From 1986-1992, I initiated and led the first suture development program at U.S. Surgical. That program led to the commercialization of the Syneture™ suture product line. My responsibilities included all phases of surgical suture development from concept to commercialization. My suture group included seventeen team members directly involved in the design and development of commercial surgical suture products, including suture design and manufacture, fiber extrusion and processing, fiber design, yarn design, braiding specifications, selection of materials, braid design, prototype braiding, braid post

limitation. Given this additional difference of claim 9 and the lack of any motivation to form a suture having this limitation, claim 9 is for this additional reason non-obvious.

VII. It Is My Opinion That All of the Claims of the 446 Patent Are Not Invalid For Failing To Satisfy The Written Description & Enablement Requirements

A. The 446 Patent is Not Invalid for Failing to Satisfy the Written Description Standard

149. Dr. Mukherjee opines that all of the claims of the 446 Patent are invalid for failing to satisfy the written description standard. According to Dr. Mukherjee, the 446 Patent "does not reasonably convey to one of ordinary skill in the art that the inventors had possession of UHMWPE" (Mukherjee at 22). Since this is the only issue that Dr. Mukherjee has raised with respect to written description, it is the only one that I address. I disagree with his opinion. The 446 Patent does reasonably convey to one of skill in the art that the inventors had possession of the claimed suture with UHMW PE as the first-fiber forming material.

150. My opinion is supported by the 446 Patent's text. The 446 Patent specifically claims "PE." Further, the 446 Patent expressly describes "polyethylene (PE)" (Ex. 2 at 4:27,30). One of skill in the art would have known that "PE" means "polyethylene" and means all polymers made from ethylene. PE is the generic name for all types of PE, including UHMW PE. In 1987, the Encyclopedia of Polymer Science and Engineering 2^{nd} edition volume 10 recognized polyethylene as the "common (source-based)" name for all polymers made from ethylene (Ex. 18). Further, the IUPAC officially recognized that PE is the accepted abbreviation for all types of PE (Ex. 19). Thus, one of skill in the art would have known that "PE" or "polyethylene" as used in the 446 Patent means all polymers from ethylene including UHMW PE.

EXHIBIT 8

ENCYCLOPEDIA OF POLYMER SCIENCE AND ENGINEERING

VOLUME 10

Molecular Weight Determination to Pentadiene Polymers

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NOMENCLATURE

Nomenclature, as used in this article, refers to the naming of polymeric materials. The nomenclature of scientific communication is emphasized, although there is generally little reason for differences between scientific and other, eg, commercial, usage.

Since the publication of the first edition of this Encyclopedia, the International Union of Pure and Applied Chemistry (IUPAC) has established the Commission on Macromolecular Nomenclature, which is now the leading nomenclature body in the polymer field. The Commission is promulgating a series of rules and definitions that are placing polymer nomenclature on a much more systematic basis than had previously been the case (Table 1) (1–21). The International Standardization Organization (ISO), primarily through its Technical Committee TC/61 Plastics, and various national nomenclature bodies (such as that of the American Chemical Society) are also helping to shape the field. Recent issues of *Chemical Abstracts* are additional authoritative sources of polymer nomenclature.

At the present time, the IUPAC Commission on Macromolecular Nomenclature is developing a set of definitions for many of the basic terms dealing with polymer molecules, assemblies of polymer molecules, polymer solutions, polymer crystals, polymer melts and solids, polymerization reactions, etc. It is also extending existing nomenclature to more complicated cases, such as cross-linked polymers. When this phase of the work is completed by the late 1980s, the naming of polymers and polymer terminology will have become largely systematized and, following the IUPAC practice in other fields of chemistry, a compendium of polymer nomenclature rules will be published.

Table 1. IUPAC Publications on Polymer Nomenclature

Title	Comment	Refs.
Report on Nomenclature in the Field of Macromolecules	obsolete	1
Report on Nomenclature Dealing with Steric Regularity in High Polymers	superseded by Ref. 2	3
Revised Report on Nomenclature Dealing with Steric Regularity in High Polymers	superseded by Ref. 4	2,5
Report of the Committee on Nomenclature of the International Commission on Macromolecules	obsolete	6
Basic Definitions of Terms Relating to Polymers		7,8
List of Standard Abbreviations (Symbols) for Synthetic Polymers and Polymer Materials (1974)	superseded by Ref. 9	10
Use of Abbreviations for Names of Polymeric Substances	Recommendations 1986	9
Nomenclature of Regular Single-Strand Organic Polymers		11
Stereochemical Definitions and Notations Relating to Polymers	Provisional Recommendations 1980	12 4
Nomenclature for Regular Single-Strand and Quasi Single-Strand Inorganic and Coordination Polymers	Provisional Recommendations 1984	13 14
Note on the Terminology for Molar Masses in Polymer Science		15–17
Source-Based Nomenclature for Copolymers		18
Definitions of Terms Relating to Individual Macromolecules, Their Assemblies, and Dilute Polymer Solutions		19
Definitions of Terms Relating to Crystalline Polymers		20
A Classification of Linear Single-Strand Polymers		21

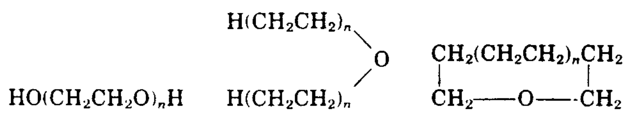
Basic Definitions

No nomenclature document is more fundamental to a given science than the definitions of basic terms used in that area. The IUPAC Commission on Macromolecular Nomenclature published a document in 1974 (8) that offers definitions of 52 terms, including polymer, constitutional unit, monomer, polymerization, regular polymer, tactic polymer, block polymer, graft polymer, monomeric unit, degree of polymerization, addition polymerization, condensation polymerization, homopolymer, copolymer, bipolymer, terpolymer, copolymerization, and many others. Both structure-based and process-based definitions are given.

Source-based Nomenclature

Traditionally, polymers have been named by attaching the prefix poly to the name of the real or assumed monomer (the "source") from which it is derived.

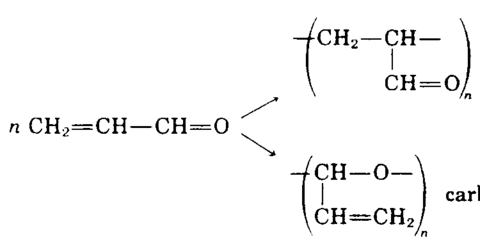
Thus polystyrene is the polymer made from styrene and will often be found in an index under "styrene, polymer of." When the name of the monomer consists of two or more words, parentheses should be used (1), as in poly(vinyl acetate), poly(methyl methacrylate), poly(sodium styrenesulfonate), etc. Failure to use parentheses can lead to ambiguity: polychlorostyrene can be the name of either a polychlorinated (monomeric) styrene molecule or a polymer derived from chlorostyrene; polyethylene oxide can refer to polymer (**1**), polymer (**2**), or the macrocycle (**3**).



(1) (2) (3)

These problems are easily overcome with parentheses; names such as poly(chloro)styrene, poly(chlorostyrene), and poly(ethylene oxide) clearly indicate the part of the name to which the prefix poly refers. The omission of parentheses is, unfortunately, quite common.

The principal deficiency of source-based nomenclature is that the chemical structure of the monomeric unit in a polymer is not identical with that of the monomer, eg, $—CH_2—CHX—$ vs $CH_2{=}CHX$; thus the name polymonomer is actually a misnomer. The structure of the repeating unit is also not specified in this scheme; for example, polyacrolein does not indicate whether the vinyl or the aldehyde group has polymerized (see ACROLEIN POLYMERS).



Different types of polymerization can take place with many other monomers, depending on the polymerization conditions. Furthermore, a name such as poly(vinyl alcohol) refers to a hypothetical source, since this polymer is obtained by hydrolysis of poly(vinyl acetate). In spite of these serious deficiencies, source-based nomenclature is still firmly entrenched in industrial literature and, to a lesser extent, in scientific communication. It originated at a time when polymer science was less developed and the structure of most polymers ill-defined. The rapid advances now being made in structural determination of polymers will gradually shift the emphasis of polymer nomenclature away from starting materials and toward the structure of the macromolecules.

Copolymers. Copolymers are polymers that are derived from more than one species of monomer (8). Because this is a process-based definition, source-based nomenclature can be easily adapted to the naming of copolymers (18). However, the arrangement of the various types of monomeric units must be specified. Seven types of arrangements have been defined and are shown in Table where A, B, and C represent the names of monomers. The monomer names are linked through a connective (infix), such as *-co-*, to form the name of the copolymer, as in poly(styrene-*co*-acrylonitrile). The order of citation of the mono-

mers is arbitrary, except for graft copolymers where the backbone monomer is named first.

An equally acceptable alternative scheme utilizes the prefix copoly followed by citation of the names of the monomers used, separated from each other by an oblique stroke. Parentheses are also needed. For example, copoly(styrene/butadiene) denotes an unspecified copolymer of styrene and butadiene. The other connectives of Table 2 are placed before such names to provide additional structural information, as in

stat-copoly(styrene/butadiene)
ran-copoly(ethylene/vinyl acetate)
alt-copoly(styrene/maleic anhydride)
per-copoly(ethylene phenylphosphonite/methyl acrylate/carbon dioxide)
block-copoly(styrene/butadiene/methyl methacrylate)
graft-copoly(styrene/butadiene)

It is not necessary to use parentheses to enclose vinyl acetate, maleic anhydride, methyl acrylate, etc, even though the name of each of these monomers consists of two words; the names of the polymers, as written here, are unambiguous.

The names of copolymers, derived either from the main scheme or the alternative, can be further modified to indicate various structural features. For example, the chemical nature of end groups can be specified as follows:

α-X-ω-Y-poly(A-*alt*-B)
α-butyl-ω-carboxy-*block*-copoly(styrene/butadiene)

Whereas subscripts placed immediately after the name of the monomer or the block designate the degree of polymerization or repetition, mass and mole fractions and molar masses, which in most cases are average quantities, are expressed by placing corresponding figures after the complete name of the copolymer. The order of citation is as for the monomeric species in the name. Unknown quantities are designated by *a*, *b*, etc. Some examples follow.

A block copolymer containing 75 mass % of polybutadiene and 25 mass % of polystyrene is

polybutadiene-*block*-polystyrene (0.75:0.25 w) or
block-copoly(butadiene/styrene) (75:25 mass %)

A graft copolymer, consisting of a polyisoprene backbone grafted with isoprene and acrylonitrile units in an unspecified arrangement, containing 85 mol % of isoprene units and 15 mol % of acrylonitrile units is

polyisoprene-*graft*-poly(isoprene-*co*-acrylonitrile) (0.85:0.15 x) or
graft-copoly[isoprene/(isoprene;acrylonitrile)] (85:15 mol %)

A graft copolymer consisting of 75 mass % of polybutadiene with a relative molecular mass of 90,000 as the backbone and 25 mass % of polystyrene in grafted chains with a relative molecular mass of 30,000 would be

polybutadiene-*graft*-polystyrene (75:25 mass %; 90,000:30,000 M_r)

Table 2. IUPAC Nomenclature of Copolymers[a]

Type	Arrangement of monomeric units	Structure	Connective	Example
unspecified	unknown or unspecified	(A-*co*-B)	-*co*-	poly[styrene-*co*-(methyl methacrylate)]
statistical	obeys known statistical laws	(A-*stat*-B)	-*stat*-	poly(styrene-*stat*-acrylonitrile-*stat*-butadiene)
random	obeys Bernoullian statistics	(A-*ran*-B)	-*ran*-	poly[ethylene-*ran*-(vinyl acetate)]
alternating	alternating sequence	$(AB)_n$	-*alt*-	poly[(ethylene glycol)-*alt*-(terephthalic acid)]
periodic	periodic with respect to at least three monomeric units	$(ABC)_n$ $(ABB)_n$ $(AABB)_n$ $(ABAC)_n$	-*per*-	poly[formaldehyde-*per*-(ethylene oxide)-*per*-(ethylene oxide)]
block	linear arrangement of blocks	—AAAAA—BBBBBB—	-*block*-[b]	polystyrene-*block*-polybutadiene
graft	polymeric side chain different from main chain[c]	—AAAAAAAAAAAA— | B B B B B |	-*graft*-[d]	polybutadiene-*graft*-polystyrene

[a] Main system of the IUPAC document (18); an alternative scheme is described in the text.
[b] The connective -*b*- has also been used.
[c] Main chain (or backbone) is specified first in the name.
[d] The connective -*g*- has also been used.

A graft copolymer in which the polybutadiene backbone has a DP of 1700 and the polystyrene grafts have an unknown DP is named

graft-copoly(butadiene/styrene) (1700:*a* DP)

The published IUPAC copolymer document (18) should be consulted for the names of more complex copolymers, eg, those having a multiplicity of grafts or having chains radiating from a central atom (see also BLOCK COPOLYMERS; COPOLYMERS, ALTERNATING; COPOLYMERIZATION; GRAFT COPOLYMERS).

Structure-based Nomenclature

For organic polymers that are regular, ie, have only one species of constitutional unit in a single sequential arrangement, and consist only of single strands, the IUPAC has promulgated a structure-based system of naming polymers (11). As originally devised by the Polymer Nomenclature Committee of the American Chemical Society (22), it consists of naming a polymer as poly(constitutional repeating unit), wherein the repeating unit is named as a bivalent organic radical according to the usual nomenclature rules for organic chemistry. It is important to note that in structure-based nomenclature the name of the constitutional repeating unit has no relationship to the source from which the unit was prepared. The name is simply that of the largest identifiable unit in the polymer, and locants for unsaturation, substituents, etc are dictated by the structure of the unit.

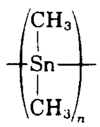
The steps involved in naming the constitutional repeating unit are (*1*) identification of the unit, taking into account the kinds of atoms in the main chain and the location of substituents; (*2*) orientation of the unit; and (*3*) naming of the unit. Examples of names for some common polymers are given in Table 3. Note that in this system parentheses are always used to enclose the repeating unit.

Structure-based nomenclature can be utilized to name polymers with great complexity, provided only that they be regular and single-stranded. Among these are polymers with constitutional repeating units which consist, themselves, of a series of smaller subunits; polymers with heteroatoms or heterocyclic ring systems in the main chain; and polymers with substituents on acyclic or cyclic subunits of constitutional repeating units. Structure-based nomenclature is also applicable to copolymers having a regular structure, regardless of the starting materials used, eg, poly(oxyethyleneoxyterephthaloyl). In principle, it should be possible to extend the existing structure-based nomenclature beyond regular, single-strand polymers to polymers that have reacted, cross-linked polymers, ladder polymers, and other more complicated systems.

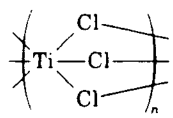
Structure-based nomenclature has gained acceptance in the scientific literature, eg, *Chemical Abstracts*, because it overcomes many of the deficiencies of source-based nomenclature.

Inorganic and Coordination Polymers. The nomenclature of regular single-strand inorganic and coordination polymers (qv) is governed by the same

ındamental principles as that for single-strand organic polymers (14). The name ˋ such a polymer is that of the smallest structural repeating unit prefixed by ıe terms poly, *catena* (for linear chains) or other structural indicator, and des- nations for end groups. The structural units are named by the nomenclature ıles for inorganic and coordination chemistry. Some examples are



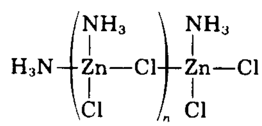
catena-poly[dimethyltin]



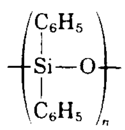
catena-poly[titanium-tri-μ-chloro]

$-\!(N{=}S)_n\!-$

catena-poly[nitrogen-μ-thio]



α-ammine-ω-(amminedichlorozinc)-*catena*-poly[(amminechlorozinc)-μ-chloro]



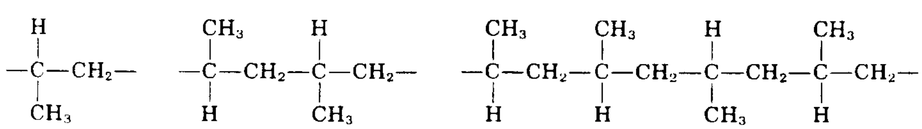
catena-poly[(diphenylsilicon)-μ-oxo]

$-\!(Ag{-}NC)_n\!-$

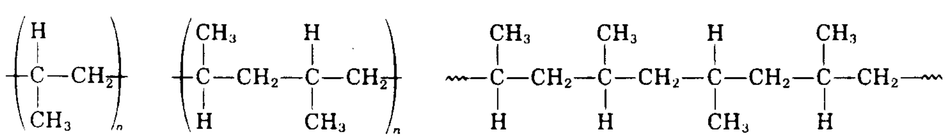
catena-poly[silver-μ-(cyano-*N*:*C*)]

.ereochemical Definitions and Notations. Structure-based nomenclature regular polymers (4) can denote stereochemical features if the repeating unit ,ed is the configurational unit, ie, a constitutional unit having one or more sites defined stereoisomerism (8). Structure-based names are then derived in the ,ual fashion. The various stereochemical features that are possible in a polymer ust be defined.

Natta and co-workers introduced the concept of tacticity, ie, the orderliness the succession of configurational repeating units in the main chain of a polymer. ır example, in poly(propylene), possible steric arrangements are shown in Fischer ojections displayed horizontally:



.d the corresponding polymers have the following structures:

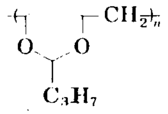
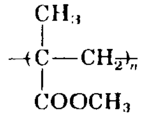
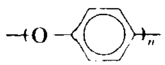
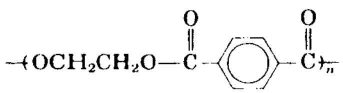
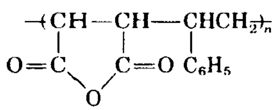


ısotactic syndiotactic atactic

The isotactic polymer has only one species of configurational unit in a single ʇuential arrangement and the syndiotactic polymer shows an alternation of ınf ational units that are enantiomeric, whereas in the atactic polymer the

Table 3. Examples of Systematic Structure-based Names for Polymers[a]

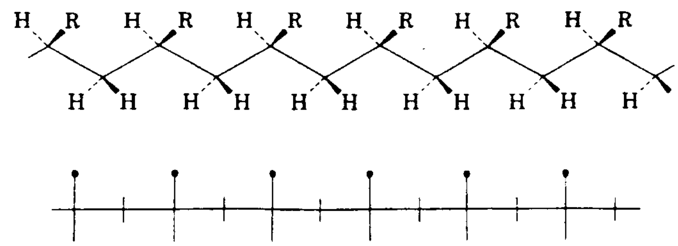
Structure	Structure-based name	Common (source-based) name
$-(CH_2CH_2)_n-$	poly(methylene)	polyethylene
$-(\underset{\lvert \atop CH_3}{C}HCH_2)_n-$	poly(propylene)	polypropylene
$-(\overset{CH_3 \atop \lvert}{\underset{\lvert \atop CH_3}{C}}-CH_2)_n-$	poly(1,1-dimethylethylene)	polyisobutylene
$-(\underset{\lvert \atop CH_3}{C}=CHCH_2CH_2)_n-$	poly(1-methyl-1-butenylene)	polyisoprene
$-(\underset{\lvert \atop C_6H_5}{C}HCH_2)_n-$	poly(1-phenylethylene)	polystyrene
$-(\underset{\lvert \atop Cl}{C}HCH_2)_n-$	poly(1-chloroethylene)	poly(vinyl chloride)
$-(\underset{\lvert \atop CN}{C}HCH_2)_n-$	poly(1-cyanoethylene)	polyacrylonitrile
$-(\underset{\lvert \atop OOCCH_3}{C}HCH_2)_n-$	poly(1-acetoxyethylene)	poly(vinyl acetate)
$-(\overset{F \atop \lvert}{\underset{\lvert \atop F}{C}}CH_2)_n-$	poly(1,1-difluoroethylene)	poly(vinylidene fluoride)

$-(CF_2)_n-$	poly(difluoromethylene)	polytetrafluoroethylene
	poly[(2-propyl-1,3-dioxane-4,6-diyl)methylene]	poly(vinyl butyral)
	poly[1-(methoxycarbonyl)-1-methylethylene]	poly(methyl methacrylate)
$-(OCH_2CH_2)_n-$	poly(oxyethylene)	poly(ethylene oxide)
	poly(oxy-1,4-phenylene)	poly(phenylene oxide)
	poly(oxyethyleneoxyterephthaloyl)	poly(ethylene terephthalate)
$-[NH-\overset{O}{\overset{\Vert}{C}}(CH_2)_4\overset{O}{\overset{\Vert}{C}}-NH(CH_2)_6]_n-$	poly(iminoadipoyliminohexamethylene)	poly(hexamethylenediamine-*co*-adipic acid) or poly(hexamethylene adipamide)
	poly[2,5-dioxotetrahydrofuran-3,4-diyl(phenylethylene)]	poly(maleic anhydride-*co*-styrene)

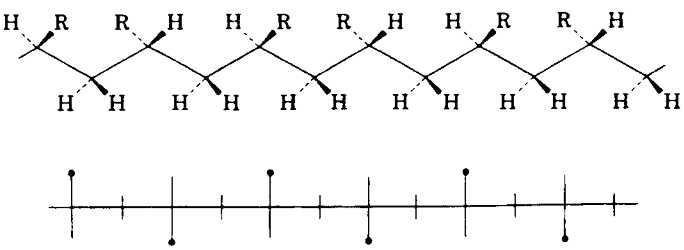
[a] Ref. 6. Courtesy of *Pure and Applied Chemistry*.

molecules have equal numbers of the possible configurational units in a random sequence distribution. This can be generalized as follows:

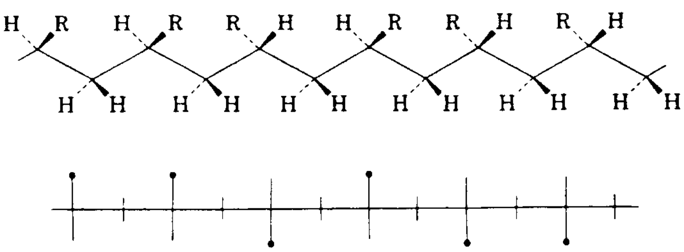
Isotactic:



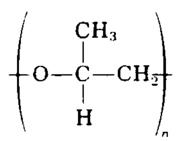
Syndiotactic:



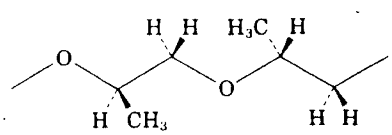
Atactic:

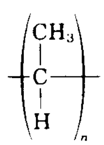


Further examples of tactic polymers are

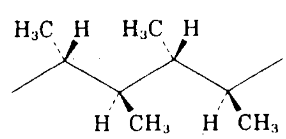


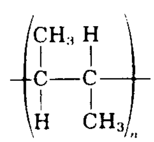
isotactic poly(oxypropylene)



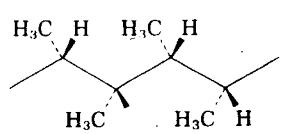


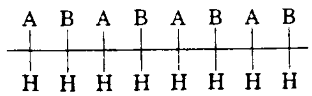
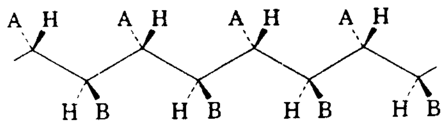
isotactic poly(ethylidene)



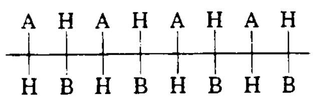
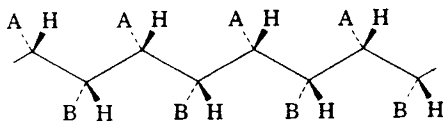


syndiotactic poly(ethylidene)

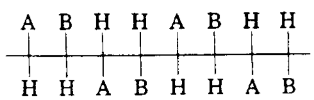
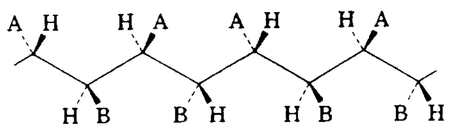


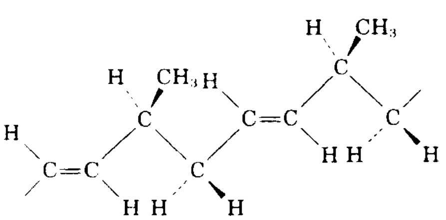
erythrodiisotactic polymer

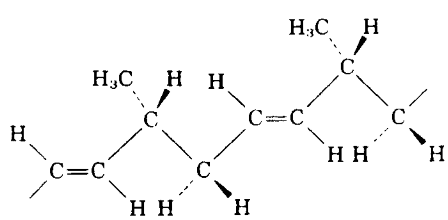
threodiisotactic polymer

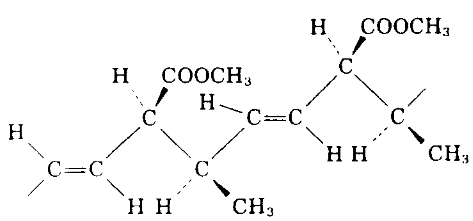
disyndiotactic polymer



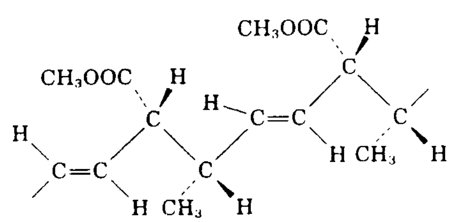
and/or



isotactic poly(3-methyl-*trans*-1-butenylene) or transisotactic poly(3-methyl-1-butenylene)

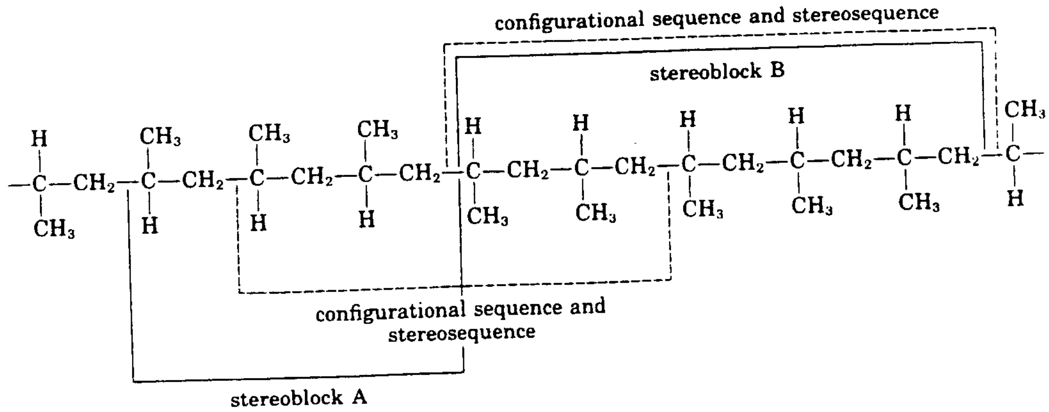


and/or



diisotactic poly[*threo*-3(methoxycarbonyl)-4-methyl-*trans*-1-butenylene] or transthreodiisotactic poly[3-(methoxycarbonyl)-4-methyl-1-butenylene]

The concept of a stereoblock is illustrated in the following example of a regular poly(propylene) chain, in which the stereoblocks are denoted by ┌──┐. The sequence of identical relative configurations of adjacent units that characterizes a stereoblock is terminated at each end of the block. The dashed line [illegible] encloses a configurational sequence, which may or may not be identical [illegible] a stereoblock.



The published IUPAC document (4) should be consulted for more complex cases and for the notations used to designate conformations of polymer molecules (bond lengths, bond angles, torsion angles, helix sense, isomorphous and enantiomorphous structures, line repetition groups and symmetry elements, etc) as well as for the various stereochemical definitions (see also MICROSTRUCTURE; STEREOREGULAR POLYMERS).

Trade Names and Abbreviations

Because the systematic names of polymers can be cumbersome, trade names and abbreviations are frequently used as a shortcut in industrial literature and

Table 4. List of Abbreviations from the 1986 IUPAC Recommendations[a]

PAN	polyacrylonitrile
PCTFE	polychlorotrifluoroethylene
PEO	poly(ethylene oxide)
PETP[b]	poly(ethylene terephthalate)
PE	polyethylene
PIB	polyisobutylene
PMMA	poly(methyl methacrylate)
POM	poly(oxymethylene); polyformaldehyde
PP	polypropylene
PS	polystyrene
PTFE	polytetrafluoroethylene
PVAC	poly(vinyl acetate)
PVAL	poly(vinyl alcohol)
PVC	poly(vinyl chloride)
PVDC	poly(vinylidene dichloride)
PVDF	poly(vinylidene difluoride)
PVF	poly(vinyl fluoride)

[a] Ref. 9.
[b] The abbreviation PET is commonly used in the literature.

oral communication. For example, the simpler generic name nylon-6,6 for a polyamide, where the first number refers to the number of carbon atoms of the diamine and the second number to that of the diacid fragment, appears often in the literature rather than the systematic name poly(iminoadipoyliminohexamethylene). Useful compilations of trade names for polymers can be found in Refs. 23 and 24.

Perhaps the most widely used shortcut is the use of abbreviations for common industrial polymeric materials. The IUPAC recognizes that there may be advantages in some cases to use abbreviations, but urges that each abbreviation be fully defined the first time it appears in the text and that no abbreviation be used in titles of publications. Because there are inherent difficulties in assigning systematic and unique abbreviations to polymeric structures, only a short list has the IUPAC's official sanction (9,10) (Table 4). ISO has published a more extensive list (25), and the American Chemical Society has compiled a master list of all known abbreviations in the polymer field (26).

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NORBERT M. BIKALES
National Science Foundation
Secretary (1978–1987), IUPAC Commission on Macromolecular Nomenclature

NONAQUEOUS DISPERSIONS. See COATINGS.

NONCOMBUSTIBLE FABRICS. See FLAMMABILITY.

NONDESTRUCTIVE TESTING. See TEST METHODS.

NON-NEWTONIAN FLOW. See VISCOELASTICITY.

NONWOVEN FABRICS

SURVEY

Nonwoven fabrics are porous, textilelike materials, usually in flat she form, composed primarily or entirely of fibers assembled in webs (1–3). The fabrics, also called bonded fabrics, formed fabrics, or engineered fabrics, are ma ufactured by processes other than spinning, weaving, or knitting. The thickn of the sheets may vary from 25 μm to several centimeters, and the weight fr 10 g/m² to 1 kg/m². A sheet may resemble paper or a woven or knitted fabric appearance and may have a unique texture or pattern. It may be as compact a crisp as paper or supple and drapable as a conventional textile; it may be resili or limp. Its tensile properties may be barely self-sustaining or so high that i impossible to tear, abrade, or damage the sheet by hand. The fiber compone one or several types, may be natural or synthetic, from 1–3-mm long to endl The tensile properties may depend on frictional forces or a film-forming polym additive functioning as an adhesive binder. All or some of the fibers may welded by heat or solvent. A scrim, gauze, netting, yarn, or other conventi sheet material may be added to one or both faces, or embedded within as r forcement. The nonwoven fabric may be incorporated as a component in a c posite structure.

Felted fabrics from animal hairs, eg, wool (qv), are not included even th

an·hy·drous \(ˈ)anˈhīdrəs\ *adj* [modif. (influenced by *hydr-*, *hydro-*) of Gk *anydros* waterless, fr. *an-* + *-ydros* (fr. *hydōr* water) — more at WATER] **:** destitute of water — used of water of crystallization, dissolved or combined water, adsorbed water

EXHIBIT 9

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

C.A. NO. 04-12457 PBS

ORIGINAL

--------------------------------x

DePUY-MITEK, INC.,

A Massachusetts Corporation,

Plaintiff,

vs.

ARTHREX, INC.,

A Delaware Corporation,

Defendants.

--------------------------------x

DEPOSITION OF DR. MATTHEW HERMES

Philadelphia, Pennsylvania

June 27, 2006

Reported by:

CONSTANCE S. KENT, CSR, RPR

JOB NO.: 350

adopting its source-based nomenclature in 1985 as the nomenclature for polymers.

Q. **Okay. Now, you say in your report, IUPAC officially recognized PE as the accepted abbreviation for all types of PE, correct? That's 150.**

A. That's what I wrote, yes.

Q. **Could you tell me where in your report it says that IUPAC officially recognized PE as the accepted abbreviation for all types of PE? You didn't make any specific reference in the report or I couldn't find it, so perhaps you can help me.**

A. I believe I mischaracterized the reference in the report. I don't -- I may find it in reference 19, but I believe that I'm referring to reference 18.

Q. **We'll get to 18 in a moment.**

A. Fine.

Q. **But let's -- so you couldn't find it in that sentence in 19?**

A. As of this moment, I do not find that.

Q. **Okay. Could you look at 19 for just a moment.**

A. Of course.

Q. And I want to -- at the beginning of it, I guess the second page of the exhibit, where it says the abstract. Do you see that near the top?

A. Yes.

Q. It says: The commission has already published two documents on the source-based names of linear copolymers and nonlinear polymers.

Do you see that?

A. Yes.

Q. And it goes on to say that: In some cases, this nomenclature led to ambiguous names?

A. Yes.

Q. Do you believe that's accurate?

A. I have no direct knowledge as to what specifics the authors of this -- of that sentence are pointing to. Offhand I don't know what ambiguity they're pointing at.

Q. But you have no doubt -- you have no reason to doubt the author's statement about the ambiguity in some cases?

A. I have no doubt -- I have no reason to doubt the author's statement, correct.

Q. In the next sentence goes on: The present document proposes a generic source-based nomenclature that solves these problems and yields

clearer source-based names, correct?

A. Yes.

Q. **Okay. Is it your understanding that this document is designed to try and clear up an ambiguity that existed?**

A. No, it's my understanding that it's a document describing generic source-based nomenclature.

Q. **What does it mean to you when it says it solves these problems and yields clearer source-based names?**

A. Whatever problems there were, it's attempting to clear them up. I'm sorry, I'm not familiar with what the specific problems were.

Q. **But you agree with me this document in 2001 is an attempt to clear up problems that existed on names?**

A. That's what it says sir, yes.

Q. **Let's -- let's go to Exhibit 18 if we could, please.**

A. Indeed.

Q. **Could you turn to page 193 of this report?**

A. Yes.

Q. **Is it correct that this -- this**

exhibit is saying that there are deficiencies of source-based nomenclature?

A. The -- the paragraph beginning the principal deficiency talks in general about a nomenclature problem that has been inherent in defining the names of polymers, yes.

Q. And if you look further down the paragraph, doesn't it conclude, the paragraph: The rapid advances now being made in the structural determination of polymers will gradually shift the emphasis of polymer nomenclature away from the starting materials and toward the structure of the macromolecules?

A. That's a -- that is the opinion of the authors.

Q. Do you have any reason to disagree with the opinions of the authors?

A. I don't think I have enough knowledge to disagree with those authors.

Having said that, this was published in 1987, 20 years ago, and there's no -- there's no indication in the field of ethylene and polyethylene that anything of that kind is going on these days. Polyethylene is still polyethylene, and the -- the structural details do not appear in the source-based

EXHIBIT 10

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.,** **a Private Limited Company** **of the United Kingdom,** **Defendants.**	)	**Civil No. 04-12457 PBS**

<u>Expert Report of Dr. David Brookstein</u>

I. Background Information

A. Teaching Experience

1. I am the Dean and Professor of Engineering at the School of Engineering and Textiles of Philadelphia University. I have held this position since 1994. In 2005, I also was appointed Executive Director of Research at Philadelphia University.

2. I was a Visiting Scholar at the Harvard University Center for Textile and Apparel Research (Division of Engineering and Applied Sciences) between 2002-2003.

3. I was an Adjunct Professor in Mechanical Engineering at Northeastern University in Boston, MA from 1981-1983. At Northeastern, I taught undergraduate courses in statics, dynamics, and mechanics of deformable bodies and material science.

4. I was Assistant Professor of Textile Engineering at Georgia Institute of Technology, College of Engineering from 1975 – 1980. At Georgia Tech, I taught and

device "performs substantially the same function in substantially the same way to obtain the same result" ("function/way/result test") as the claimed element.

V. Direct Infringement

A. Claim Construction

27. As mentioned above, I understand that the first step in an infringement analysis is to construe the claims. I understand that the Court will determine the meaning of the claim terms in the '446 Patent. Until the Court determines the meaning of the claims, I have been asked to assume the meaning of the following claim terms.

"PE" – means all types of polyethylene (PE) including ultra high molecular weight polyethylene.

"consisting essentially of" – means the claimed suture with all of its limitations and any other unlisted materials that do not materially affect the basic and novel characteristics of the claimed suture.

I have been told that the Court will determine the basic and novel characteristics of the claimed invention. I have been asked to assume that the basic and novel characteristics are a heterogeneous braid of dissimilar non-bioabsorbable yarns of the type claimed, where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, and the dissimilar yarns have at least some different properties that contribute to the overall properties of the braid.

"direct intertwining contact" –means the mechanical interlocking or weaving of the individual yarns that make up the suture braid.

"volume fraction of the first set of yarns in the braided sheath and core" means the ratio of the cross-sectional area of the first set of yarns in the sheath and core to the total cross sectional area of all the yarns in the surgical suture.

56. It is my opinion that the UHMWPE in Arthrex's FiberWire™ and TigerWire™ products has the function as the claimed first fiber-forming material based on an examination of FiberWire™ and TigerWire™ and its manufacturing. In my opinion, the UHMWPE contributes a property or properties that is/are different from the property or properties contributed by the PET. For example, Mr. Hallet testified that, in the development of FiberWire™, he had constructed a 100% homogeneous UHMWPE braid, but Arthrex had requested a less stiff braid. Mr. Hallet then made a heterogeneous braid of UHMWPE and PET to get the strength of UHWMPE and the flexibility of PET (Hallet 1/12/06 Dep. at p. 306:17-307:14; DMI Ex. 324; *see also* Hallet 1/12/06 Dep. at p. 307:15-308:14; DMI Ex. 325).

57. In my opinion, the "way" of the first fiber-forming material is the same as the "way" of UHMWPE in Arthrex's FiberWire™ and TigerWire™ suture products:

Claims 1, 2, 8, 9, and 12 Limitation	**"Way" of Limitation Under the Doctrine of Equivalents**	**Way UHMWPE performs its Function in FiberWire™ and TigerWire™**
a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and	The "way" is at least one yarn from the first set of yarns is in direct intertwining contact with at least one yarn from the second set.	At least one UHMWPE yarn is braided with at least one PET yarn in direct intertwining contact (Dreyfuss 9/16/05 Dep. at p. 99-107).

58. My opinion regarding the "way" of the "first fiber-forming" element is supported by the '446 Patent. The '446 Patent explains that the way that the first-fiber forming material performs its function is by braiding it with a second dissimilar yarn in direct intertwining contact For example, the '446 Patent states in the "Summary of the Invention" section that the "the invention is a heterogeneous braid comprising a first and second set of discrete yarns in a sterilized, braided construction" and that the at least one yarn from the first set is in "direct

EXHIBIT 11

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
C.A. NO. 04-12457 PBS

COPY

DePUY MITEK, INC., Plaintiffs,	)
vs.	)
ARTHREX, INC., a Delaware corporation, Defendants.	)

DEPOSITION of DR. MARK G. STECKEL, called as a witness by and on behalf of the Defendant, pursuant to the applicable provisions of the Federal Rules of Civil Procedure, before P. Jodi Ohnemus, Notary Public, Certified Shorthand Reporter, Certified Realtime Reporter, and Registered Merit Reporter, within and for the Commonwealth of Massachusetts, at the Courtyard Marriott, 423 Speen Street, Natick, Massachusetts, on Thursday, 26 January, 2006, commencing at 10:44 a.m.

would be an acceptable suture?

MR. BONELLA: Objection. Asked and answered.

A. We had a belief that it could lead to -- as you're saying -- an acceptable suture. There were other issues that we didn't know. For example, how the -- how polyethylene behaved in the body. So, it was a high priority. Polyethylene, even though there was an interest, it wasn't a -- it wasn't something that was a high priority at the time.

Q. The thought didn't cross your mind that, Oh, this would make an unacceptable suture to put Dyneema together with PET?

A. My recollection was -- an unacceptable suture or an acceptable?

Q. An unacceptable suture.

A. Well, the concern with any of the very high-strength fibers was always knot strength, and that was true whether it was Dyneema, Spectra, Kevlar, etcetera. So, the general view was, I mean, all of those -- 100 percent, all of those, Ethicon evaluated at one point as a suture material. They're the world's biggest suture material company. And all of them there was an

interest in how do you improve the knot strength of them, and can you -- that was -- that was something we discussed.

Q. I'm not sure I understand your answer.

A. Go ahead.

Q. And I'm trying to --

A. Sure.

Q. When you had this idea that you could blend Dyneema together with PET, were you -- did you believe it would make an acceptable suture or an unacceptable suture?

A. No. We believed -- we believed that that could offer a suture with straight tensile that was better than Ethibond, and you know, could potentially solve the knot issues, and again, that was a generic view for all of the high-tenacity fibers.

Q. You thought it was a good idea --

A. Yes. Yes.

Q. -- rather than a bad idea?

A. No, we viewed -- we viewed that as a potential good idea.

Q. And you didn't think, Oh, that's a bad idea.

MR. BONELLA: Objection. Asked and